(13)

No. 83-1925-AFX
Status: GRANTED

Title: Hillsborough County, Florida, et al., Appellants
v.
Automated Medical Laboratories, Inc.

Docketed:
May 23, 1984

Court: United States Court of Appeals
for the Eleventh Circuit

Counsel for appellant: Mount, Joe Horn

Counsel for appellee: Stumpf, Larry A.

Entry	Date	Note	Proceedings and Orders
1	May 23 1984	G	Statement as to jurisdiction filed.
2	Jun 28 1984		Motion of appellee Automated Med. Laboratories to affirm filed.
3	Jul 2 1984		DISTRIBUTED. September 24, 1984
4	Oct 1 1984	P	The Solicitor General is invited to file a brief in this case expressing the views of the United States.
5	Dec 14 1984		Brief amicus curiae of United States filed.
6	Dec 19 1984		REDISTRIBUTED. January 11, 1985
7	Jan 14 1985		PROBABLE JURISDICTION NOTED. Justice Powell OUT. **********
8	Feb 19 1985		Record filed.
9	Feb 19 1985		Certified original record on appeal and C.A. proceedings, 6 volumes, received.
10	Feb 27 1985		Brief of appellant Hillsborough Co., FL filed.
11	Mar 4 1985		Joint appendix filed.
12	Feb 28 1985		Brief amicus curiae of Natl. Association of Counties, et al. filed.
13	Mar 4 1985		Brief amicus curiae of United States filed.
14	Mar 11 1985	G	Motion of American Blood Resources Association for leave to participate in oral argument as amicus curiae and for divided argument filed.
15	Mar 6 1985	G	Motion of the Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument filed.
16	Mar 18 1985		Motion of American Blood Resources Association for leave to participate in oral argument as amicus curiae and for divided argument GRANTED. Justice Powell OUT.
17	Mar 18 1985		Motion of the Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument GRANTED. Justice Powell OUT.
18	Mar 15 1985		SET FOR ARGUMENT. Tuesday, April 16, 1985. (3rd case).
19	Mar 22 1985		CIRCULATED.
20	Mar 27 1985	G	Motion of the Solicitor General to permit Paul J. Larkin, Jr., Esquire, to present oral argument pro hac vice filed.
21	Mar 28 1985	X	Brief amicus curiae of American Blood Commission filed.
23	Mar 29 1985	X	Brief of appellee Automated Medical Laboratories, Inc. filed.
24	Mar 29 1985		Lodging received. (10 copies - box).
25	Mar 29 1985	X	Brief amicus curiae of American Blood Resources Assn., et

21

No. 83-1925-AFX

Entry	Date	Note	Proceedings and Orders
			al. filed.
26	Mar 29 1985	X	Brief amicus curiae of Grocery Manufacturers of America, Inc. filed.
27	Apr 9 1985	X	Reply brief of appellant Hillsborough Co., FL filed.
28	Apr 15 1985		Motion of the Solicitor General to permit Paul J. Larkin, Jr., Esquire, to present oral argument pro hac vice GRANTED.
29	Apr 16 1985		ARGUED.

83-1925

No._____

IN THE

Supreme Court of the United States

OCTOBER TERM, 1983

HILLSBOROUGH COUNTY, FLORIDA AND
HILLSBOROUGH COUNTY HEALTH DEPARTMENT
v.
AUTOMATED MEDICAL LABORATORIES, INC.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE ELEVENTH CIRCUIT

JURISDICTIONAL STATEMENT

DOUGLAS R. GARDNER
Counsel of Record
Assistant County Attorney
Member, United States
Supreme Court Bar
Post Office Box 1110
Tampa, Florida 33601
(813) 272-5670

EMELINE C. ACTON
DOLORES D. MENENDEZ
Assistant County Attorneys
Members, United States Court
of Appeals for The Eleventh
Circuit Bar
Post Office Box 1110
Tampa, Florida Box 1110
Tampa, Florida 33601

60 pp

QUESTION PRESENTED

Whether Hillsborough County Ordinances 80-11 and 80-12 and the rules and regulations promulgated thereunder regulating collection of blood plasma from paid donors are preempted by the federal regulatory scheme establishing standards and procedures for plasmapheresis operations.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

No._____

IN THE

Supreme Court of the United States

OCTOBER TERM, 1983

HILLSBOROUGH COUNTY, FLORIDA AND
HILLSBOROUGH COUNTY HEALTH DEPARTMENT
v.
AUTOMATED MEDICAL LABORATORIES, INC.

ON APPEAL FROM THE UNITED STATES DISTRICT
COURT FOR THE ELEVENTH CIRCUIT

JURISDICTIONAL STATEMENT

DOUGLAS R. GARDNER
Counsel of Record
Assistant County Attorney
Member, United States
Supreme Court Bar
Post Office Box 1110
Tampa, Florida 33601
(813) 272-5670

EMELINE C. ACTON
DOLORES D. MENENDEZ
Assistant County Attorneys
Members, United States Court
of Appeals for The Eleventh
Circuit Bar
Post Office Box 1110
Tampa, Florida Box 1110
Tampa, Florida 33601

OPINIONS BELOW

The opinion (App. B, pp. A-13 - A-19) and final judgment (App. C, p. A-20) of the United States District Court for the Middle District of Florida, William J. Castagna, J., are not reported. The opinion of the United States Court of Appeals for the Eleventh Circuit (App. A, pp. A-1 - A-12) is reported at 722 F.2d 1526.

JURISDICTION

The judgment of the United States Court of Appeals for the Eleventh Circuit (App. D, p. A-21) declaring that Hillsborough County Ordinances 80-11 and 80-12 and the implementing rules and regulations are preempted by the federal scheme regulating plasma and, therefore, invalid was entered on January 16, 1984. A Petition for Rehearing By Panel was filed by Hillsborough County, Florida on February 4, 1984 (App. E, pp. A-22 - A-25). The Eleventh Circuit Court of Appeals entered an Order denying the Petition for Rehearing on February 23, 1984. (App. F, p. A-26). A Notice of Appeal to the United States Supreme Court (App. G, pp. A-27 - A-28) was filed by Hillsborough County, Florida in the United States Court of Appeals for the Eleventh Circuit on April 20, 1984. The jurisdiction of this Court is invoked under 28 *U.S.C.* §1254(2), which provides for a direct appeal to the United States Supreme Court from a decision of a federal court holding a state statute to be unconstitutional. The United States Supreme Court has held that, for purposes of invoking the jurisdiction of the United States Supreme Court under 28 *U.S.C.* §1254(2), local ordinances are treated as state statutes, *City of New Orleans v. Dukes*, 427 U.S. 297, 96 S.Ct. 2513 (1976); *Doran v. Salem Inn, Inc.*, 422 U.S. 922, 95 S.Ct. 2561 (1975); *City of Chicago v. Atchison, Topeka and Santa Fe Railway Co.*, 357 U.S. 77, 78 S.Ct. 1063 (1958).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The citations for the constitutional provisions, statutes, ordinances and regulations involved in this case are as follows:

United States Constitution, Article 6, Clause 2, states that:

> Clause 2. Supreme Law of Land
> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

21 C.F.R. 600.3 - 680.26 (1983)

Hillsborough County Ordinances 80-11 and 80-12 and the rules and regulations promulgated thereunder. The pertinent texts of these ordinances and regulations are set forth in the Appendix. (App. H, pp. A-29 - A-42).

STATEMENT OF THE CASE

Automated Medical Laboratories, Inc. ("AML"), which operates a plasma collection center known as Tampa Plasma Center ("TPC") in Hillsborough County, Florida, filed a twelve-count complaint in the U.S. Court for the Middle District of Florida against Hillsborough County, Florida ("County") and the Hillsborough County Health Department challenging the constitutionality of Hillsborough County Ordinances 80-11 and 80-12 and the implementing rules and regulations. (App. F, p. A-26). The first count alleged that the federal government had preempted the area of plasma collection by issuing the regulations contained in 21 C.F.R. 600.3 - 680.26 (1983). Following a non-jury trial, United States District Court Judge William J. Castagna rejected all of AML's constitutional attacks on the local legislation, including AML's federal preemption attack, except for the claim that §7 of Ordinance 80-12 and §4 of the rules

and regulations imposed an impermissable burden on interstate commerce. (App. B, pp. A-13 - A-19).

AML appealed the Judgment of the District Court upholding the validity of the local legislation to the Eleventh Circuit. The County cross-appealed that portion of the Judgment which held that §7 of Ordinance 80-12 and §4 of the rules and regulations were invalid.

In its appeal to the Eleventh Circuit, AML challenged the purpose and necessity of the local legislation, the cost of compliance with it, and whether it imposed an impermissable burden on interstate commerce. The County's cross-appeal dealt with whether those two sections which were held invalid by the District Court in fact constituted an impermissable burden on interstate commerce.

Neither party raised the issue of federal preemption in the appeal. In fact, the preemption issue was raised only by the *amicus curiae* brief of the American Blood Resources Association ("ABRA") and the Florida Association of Plasmapheresis Establishment ("FAPE") which was filed by leave of court subsequent to the submission of the County's Answer Brief. Although the County specifically requested the opportunity to respond to the new issues raised by the *amicus* brief in its Motion for Rehearing or Clarification of the Court's Order granting leave for ABRA/FAPE to file an untimely *amicus* brief (App. I, pp. A-43 - A-46), that opportunity was denied by the Court in its Order filed on August 2, 1983. (App. J, p. A-47). The Court entered that Order even though Fed. R. App. p. 29 provides as follows: "Save as all parties otherwise consent, any *amicus curiae* shall file its brief within the time allowed the party whose position as to affirmance or reversal the *amicus* brief will support *unless the Court for cause shown shall grant leave for later filing, in which event it shall specify within what time an opposing party may answer*". (Emphasis supplied).

In its Opinion (App. A, pp. A-1 - A-12) entered on January 16, 1984, the Eleventh Circuit Court of Appeals held that,

though no express preemption existed, the County ordinances and regulations were implicitly preempted by federal regulation, as the pervasiveness of the federal regulatory scheme made it reasonable to infer that Congress left no room for local ordinances to supplement it, that the federal interest in plasmapheresis was dominant over any local interest, and that the enforcement of state law would present a serious danger of conflict with the administration of the federal program. Thus, the Eleventh Circuit Court declined to reach any of the other issues raised on appeal. Further, the Court failed to address the point raised by Hillsborough County in its cross-appeal. Accordingly, the District Court's judgment finding Section 7 of Ordinance 80-12 and Section 4 of the County rules and regulations invalid was affirmed, and the judgment finding the remaining sections of the County ordinances and rules and regulations valid was reversed by the Eleventh Circuit Court of Appeals.

STATEMENT OF THE REASONS WHY THE QUESTION PRESENTED IS SUBSTANTIAL

The question presented as to whether the federal regulatory scheme implicitly preempted the area of regulation of plasma collection is a substantial one because it not only affects the ability of Hillsborough County to enact such legislation for the protection of the health, safety and welfare of its local residents, but would also preclude other state and local governments within the jurisdiction of the Eleventh Circuit Court of Appeals from enacting legislation to regulate plasma collection in their areas. The decision by the Eleventh Circuit Court of Appeals that the area of plasma regulations has been implicitly preempted by the federal government due to the pervasiveness of the federal regulatory scheme constitutes an intrusion into an area of peculiarly local concern — the public health, safety and welfare. Such an intrusion into the police powers of a local government is unwarranted absent a clear intention to preempt. Where there is no explicit preemption provision in legislation passed by the federal government which allegedly conflicts with state legislation, preemption will not be presumed. *New York State Department of Social Services v. Dublino*, 413 U.S. 405 (1973). Absent an express preemption or express conflict be-

tween state and federal legislation, the legislation must be examined to determine whether they can coexist. Federal and local enactments should as a rule be accommodated and the law does not favor the ouster of local legislation. *Merrill, Lynch, Pierce, Fenner & Smith, Inc. v. Ware*, 414 U.S. 117 (1973).

Hillsborough County enacted Ordinances 80-11 and 80-12 and their companion rules and regulations while fully cognizant of the comprehensive federal regulations in the area of plasma collection. In fact, Hillsborough County expressly incorporated the federal regulations appearing at 21 C.F.R. Part 640, Subpart G, Section 640.60 *et seq*, the provisions of the federal regulatory scheme relating solely to "Source Plasma (Human)". Nevertheless, Hillsborough County went beyond the federal requirements in order to protect its residents against the dangers of cross-bleeding and of unnecessary contamination of plasma centers by hepatitus - positive plasma vendors as well as to ensure that paid donnors were capable of understanding the risks involved in the plasmapheresis process and of giving their informed consent to undergo that process. In addition, Hillsborough County provided for local inspection of plasma centers to supplement the only minimal federal inspection process. In fact, substantial evidence was presented at trial by experts in the field of plasmapheresis as well as by representatives of the federal Food and Drug Administration that Hillsborough County's plasma ordinances and regulations would be valuable supplements as to the federal regulatory scheme and would not adversely affect the national blood policy.

Just as Hillsborough County has perceived a need for local legislation regulating plasma collection, many other localities have recognized similar needs in their communities.[1] thus, the question of whether the federal regulatory scheme has preempted the area of plasma legislation is a substantial issue and worthy of this Court's consideration.

Respectfully submitted,

DOUGLAS R. GARDNER
Counsel of Record
Assistant County Attorney
Member, United States
Supreme Court Bar
Post Office Box 1110
Tampa, Florida 33601
(813) 272-5670

[1] The records of the federal Department of Biologics indicate plasma regulation in the following state and local governments: Dade County, Florida; California; Connecticut; Illinois; City of New Orleans; Michigan; New Jersey; New York; Ohio; Puerto Rico; Tennessee; Virginia; State of Florida; Georgia; Maryland; and Pennsylvania.

CERTIFICATE OF SERVICE

All parties required to be served have been served by depositing on this 23rd day of May, 1984 copies of this document in a U.S. Post Office, with first class postage prepaid, addressed to counsel of record at his or her post office address as follows:

Larry A. Stumpf, Esq.
Attorney for Automated
Suite 1000 Flagship Center
777 Brickell Avenue
Miami, Florida 33131

Amelia M. Park, Esq.
Attorney for Hillsborough County Health Department
Health & Rehabilitative Services
4000 W. Buffalo Avenue
Tampa, Florida 33614

DOUGLAS R. GARDNER
Counsel of Record
Assistant County Attorney
Member, United States
Supreme Court Bar
Post Office Box 1110
Tampa, Florida 33601
(813) 272-5670

APPENDIX

722 FEDERAL REPORTER, 2d SERIES

AUTOMATED MEDICAL LABORATORIES, INC.,
Plaintiff-Appellant,
v.
HILLSBOROUGH COUNTY, Florida, and
Hillsborough County Health Department,
Defendants-Appellees.

No. 83-3014.

United States Court of Appeals,
Eleventh Circuit.

Jan. 16, 1984.

Appeal was taken from a judgment of the United States District Court for the Middle District of Florida, William J. Castagna, J., finding that parts of county ordinances regulating collection of blood plasma from paid donors by plasmapheresis were invalid. The Court of Appeals, Tuttle, Senior Circuit Judge, held that ordinances were implicitly preempted by federal regulation, as pervasiveness of federal regulatory scheme made it reasonable to infer that Congress left no room for local ordinances to supplement it, federal interest in plasmapheresis was dominant over any local interest, and enforcement of state law would present serious danger of conflict with administration of federal program.

Affirmed in part, reversed in part.

1. States 4.10
Preemption of state law by federal statute or regulation is not favored in the absence of persuasive reasons. U.S.C.A. Const. Art. 6, cl. 2.

2. States 4.10
Touchstone of a preemption analysis is congressional intent, which may be either express or implied. U.S.C.A. Const. Art, 6, cl. 2.

3. Counties 21½
Health and Environment 33
States 4.12
County ordinances regulating collection of blood plasma from paid donors by plasmapheresis were implicitly preempted by federal regulation, as pervasiveness of federal regulatory

scheme made it reasonable to infer that Congress left no room for local ordinances to supplement it, federal interest in plasmapheresis was dominant over any local interest, and enforcement of state law would present serious danger of conflict with administration of federal program. U.S.C.A. Const. Art. 6, cl. 2; Public Health Service Act, §§ 2 et seq., 351, 42 U.S.C.A. §§ 201 et seq., 262; Federal Food, Drug, and Cosmetic Act, §§ 1 et seq., 201(g)(1), 21 U.S.C.A. §§ 301 et seq., 321(g)(1).

Larry A. Stumpf, Miami, Fla., for plaintiff-appellant.

Richard Landfield, Washington, D.C., for amicus Blood Resources Assoc. & FL Assoc. of Plasmapheresis Establishments.

Deolores D. Menendez and Emeline L. Acton, Tampa, Fla., for defendants-appellees.

Appeal from the United States District Court for the Middle District of Florida.

Before FAY and HENDERSON, Circuit Judges, and TUTTLE, Senior Circuit Judge.

TUTTLE, Senior Circuit Judge:

Appellant Automated Medical Laboratories, Inc. ("Automated") filed a civil action against appellees Hillsborough County, Florida (the "County") and Hillsborough County Health Department (the "Department") in the United States District Court for the Middle District of Florida. Appellant challenged the constitutionality of County Ordinances 80-11 and 80-12 ("County Ordinances") and the rules and regulations promulgated thereunder. Following a nonjury trial, United States District Court Judge William J. Castagna rejected all of Automated's constitutional attacks on the local legislation, including its federal preemption attack, except for the claim that § 7 of Ordinance 80-12 and § 4 of the rules and regulations imposed an impermissible burden on interstate commerce. This Court finds that the County Ordinances are pre-empted by federal regulation. Therefore, the district court holding that § 7 of Ordinance 80-12 and § 4 of the rules and regulations are invalid is affirmed, and the holding that the remainder of the County Ordinances are valid is reversed.

I. BACKGROUND

Automated is a Florida corporation that operates, through subsidiary corporations, eight blood plasma centers in the United States. One of the centers, Tampa Plasma Corporation ("TPC"), is located in Tampa, Hillsborough County, Florida. Automated's plasma centers collect blood plasma from paid donors by plasmapheresis. Plasmapheresis is a process whereby, during a single procedure, blood is removed from a human donor, the plasma is removed from the whole blood, and the red blood cells are returned to the donor. Automated sells the plasma to pharmaceutical concerns, which use it in the manufacture of pharmaceutical products such as tetanus vaccine, albumin, and anti-hemophilic factor.

Prior to the enactment of the County Ordinances, the Food and Drug Administration of the United States Department of Health and Human Services ("FDA") had issued regulations, which are contained in 21 C.F.R. §§ 600.3-680.26 (1983) (the "federal regulations"), that established standards and procedures for plasmapheresis operations. The federal regulations provide for FDA inspection of plasmapheresis facilities, establish standards for personnel and physical plants, necessitate licenses for plasmapheresis products and facilities, and establish human blood product standards, including the means to select suitable plasmapheresis donors.

In conformance with the federal regulations, TPC selects plasma donors on the basis of medical history, tests, and physical examinations. On each potential donor's initial visit, and at four-month intervals thereafter, TPC's staff physician reviews the candidate's medical history, performs a physical examination, and decides whether to reject or accept the candidate. If the candidate is accepted, the physician explains the plasmapheresis procedure as well as its associated risks and obtains the candidate's written informed consent to having the plasmapheresis procedure performed. In addition to the regularly scheduled staff physician's review and examination, nonmedical employees of TPC, who are trained and supervised by the staff physician, review the candidate's medical history prior to each donation of plasma. Nonmedical employees also determine, prior to each donation of plasma, that the candidate's weight, body temperature, blood pressure, pulse rate, serum protein, and hematocrit value are within the limits established by the federal regulations.

In conformance with the federal regulations, TPC has established procedures for eliminating from its donor population persons whose plasma could contain hepatitis virus. The staff physician rejects any candidate who has a history of viral hepatitis, a history of addiction to self-injected narcotics, or who has, within the preceding six months, had close contact with anyone having viral hepatitis, undergone major surgery, received whole blood or any human blood derivative known to be a possible source of viral hepatitis, or been tattooed. In addition, TPC sends a sample of each donation of plasma it collects to an outside laboratory operated by another wholly owned subsidiary of Automated to be tested for hepatitis contamination. If a sample is found to be contaminated, TPC destroys the unit of plasma from which the sample was taken and permanently rejects the donor from whom that unit was collected.

TPC has also established procedures for eliminating candidates who have exceeded the volume and frequency limits for plasma donations established in the federal regulations. To monitor the frequency with which a person donates plasma, TPC has established a donor identification system. At the time of a donor's first visit, TPC requires two forms of identification to establish the donor's identity. To identify the donor on subsequent visits, TPC provides the donor with an identification card, to which is affixed the donor's photograph. In addition, TPC establishes for each donor a permanent donor record file, which contains the donor's photograph and signature, as well as descriptive identifying information (address, telephone number, birthday, sex, height, eye and hair color, race, and blood type), written reports of the donor's physical examinations, signed consent forms, and written records documenting every plasma donation made. For each donation, TPC documents the date of donation, the bleed number, the donor's medical history and laboratory test results, and the volume of whole blood and red blood cells returned. By means of a permanent donor record file, TPC can deter any attempted donation which would result in a potential donor subjecting his or her health to risks by exceeding the amount and frequency limits set forth in the federal regulations.

TPC is not required by the federal regulations to coordinate its donor identification system with that of other plasma centers in the County. If, however, circumstances warrant the checking of a potential donor's identity with another plasmapheresis center, TPC's phlebotomists examine both arms of the potential

donor for signs of recent needle marks. Any potential donor who evidences recent needle marks that cannot be attributed to previous donations reflected in his or her permanent donor record file is referred to the staff physician for further evaluation.

The federal regulations provide for the inspection of TPC by an FDA official at least once every two years. The FDA inspection covers all aspects of the condition of TPC's facility, equipment, and records, as well as the methods used by TPC in collecting, processing, testing, storing, and shipping the plasma it collects. During the four years preceding the trial of this action, TPC was inspected approximately six times by the FDA. Those inspections apparently failed to reveal any deficiency in TPC's plasmapheresis operation other than a noisy fan or air conditioner in the staff physician's office, which allegedly made it difficult for one physician to communicate well with potential donors, forms that needed to be reprinted to make them clearly legible, and the observation, contested by TPC at the time of the inspection, that the staff physician had once "checked off" certain parts of a potential donor's physical examination form before actually performing them.

On November 26, 1980, the County adopted Ordinances 80-11 and 80-12. Ordinance 80-11 imposes a license tax and conditions the issuance of a license on, among other things, agreement by the blood plasma donor center to "reasonable and continuing access" by Department personnel for inspections, a public hearing, and continuously updated information regarding the owners, employees, equipment, and facilities.

The stated purpose of Ordinance 80-12 is "to provide a system for the registration and identification of and the gathering of medical data applicable to Commercial Blood Plasma Vendors as being in the common interest of the health of the people of Hillsborough County." On March 5, 1981, the Department issued rules and regulations pursuant to Ordinance 80-12. Ordinance 80-12 requires that a potential donor must undergo a medical examination and obtain a "certificate of good health" before participating in the plasmapheresis process within the County. The regulations require that a potential donor present that certificate, together with his or her own sworn affidavit stating that he or she has not been detained or treated for acute or chronic alcoholism during the preceding twelve months, to the Department. The Department then issues its own identifica-

tion card to the potential donor. This identification card permits the potential donor to undergo plasmapheresis for a period of six months only at a single specified plasmapheresis facility located within the County.

Ordinance 80-12 also requires that TPC submit to the Department on a daily basis information as to each plasmapheresis procedure performed, including the following: the date of the procedure; the name, address, age, weight, height, sex, identification number, and current hematocrit value of the donor; the results of the donor's breath analysis; the amount of whole blood removed and the proportion of red cells returned; and the results of testing for hepatitis. Neither the ordinance nor the regulations indicate what use the Department is to make of this information. Ordinance 80-12 and the regulations also require TPC to pay the Department a fee of $1.00 for each plasmapheresis procedure it performs. The purpose of this fee seems to be limited to maintaining the bureaucracy needed to store the information provided by TPC.

Ordinance 80-12 authorizes the Department to inspect TPC periodically, even though the Department apparently employs no qualified inspector. The regulations provide that such inspections shall occur at least annually. Finally, Ordinance 80-12 subjects TPC to criminal sanctions for violation of its provisions.

II. DISCUSSION

The first issue before this Court is whether County Ordinances 80-11 and 80-12 and the rules and regulations promulgated thereunder are pre-empted by the federal scheme.

[1,2] The rationale underlying the pre-emption doctrine is that the Supremacy Clause invalidates state laws that "interfere with or are contrary to, the laws of congress...." *Gibbons v. Ogden*, 9 Wheat. 1, 211, 6 L.Ed. 23 (1824). Pre-emption of state law by federal statute or regulation is not favored in the absence of persuasive reasons. *Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317, 101 S.Ct. 1124, 1130, 67 L.Ed.2d 258 (1981); *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142, 83 S.Ct. 1210, 1217, 10 L.Ed.2d 248 (1963). The touchstone of a pre-emption analysis is congressional intent, which may be either express or implied. *Fidelity Federal Savings & Loan Association v. De La Cuesta*, 458 U.S. 141, 151, 102 S.Ct. 3014, 3022, 73 L.Ed.2d 664, 675 (1982); *Jones v. Rath Packing Co.*, 430 U.S. 519, 529, 97 S.Ct. 1305, 1309, 51 L.Ed.2d 604 (1977); *Howard v. Uniroyal, Inc.*,

719 F.2d 1552 at 1555-56 (11th Cir. 1983). In *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. at 143, 83 S.Ct. at 1218, 10 L.Ed.2d 248, the Supreme Court stated a two-pronged analysis for pre-emption claims: "Does either the nature of the subject matter, ... or any explicit declaration of congressional design to displace state regulation, require [the challenged legislation] to yield to the federal [regulatory scheme]?" We must first examine the federal law for an explicit declaration of Congress's intent to pre-empt state law.

Blood and blood components are biological products subject to the Public Health Service Act, 42 U.S.C.A. § 262 (1982), and are drugs subject to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. § 321(g)(1) (1972). *See Blank v. United States*, 400 F.2d 302, 305-06 (5th Cir. 1968); *United States v. Calise*, 217 F.Supp. 705, 709 (S.D.N.Y. 1962). The Public Health Service Act establishes licensing and product standards and the Federal Food, Drug, and Cosmetic Act provides that unadulterated drugs may not be shipped in interstate commerce. Neither statute expressly precludes state action[1]. Nor do the applicable regulations explicitly dictate pre-emption[2]. *See* 21 C.F.R. §§ 600.3-680.26 (1983).

---

[1] The attorney for the American Blood Resources Association and the Florida Association of Plasmapheresis Establishment, parties who appeared as amici curiae, argue that section 351 of the Public Health Service Act explicitly expresses Congress's intent to pre-empt state law. Section 351 provides in relevant part:

> (a) No person shall sell, barter or exchange, ... or send, carry or bring for sale, barter or exchange ... any ... blood, blood component or derivative ... unless (1) such ... blood, blood component, or derivative ... has been propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license, issued by the Secretary as hereinafter authorized, ... (d) Licenses for the maintenance of establishments ... may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations .... All such licenses shall be issued, suspended, and revoked as prescribed by regulations....

42 U.S.C.A. § 262 (1982).

This Court does not find that the statute contains express language indicating pre-emption. *Cf., Armour and Company v. Ball*, 468 F.2d 76 (6th Cir. 1972), *cert. denied*, 411 U.S. 981, 93 S.Ct. 2267, 36 L.Ed.2d 957 (1973) (federal statute in question expressly provided that requirements in addition to, or different than, those made under the statute may not be imposed by any state).

[2] "Federal regulations have no less pre-emptive effect than federal statutes." *Fidelity Federal Savings & Loan Association v. De La Cuesta*, 458 U.S. 141, 151, 102 S.Ct. 3014, 3022, 73 L.Ed.2d 664 (1982) (Supreme Court found preemption where the preamble accompanying the regulations unequivocally expressed intent to pre-empt conflicting state law). *Accord, United States v. Jones*, 707 F.2d 1334, 1336-37 (11th Cir. 1983).

[3] Having found no express intent to pre-empt state law, we next examine Congress's implicit intent in enacting the federal scheme. "Where Congress has not stated specifically whether a federal statute has occupied a field in which the states are otherwise free to legislate, different criteria have furnished touchstones for decision." *Pennsylvania v. Nelson*, 350 U.S. 497, 501-02, 76 S.Ct. 477, 479-80, 100 L.Ed. 640 (1956) (footnote omitted). *Accord Howard v. Uniroyal, Inc.*, 719 F.2d 1552 at 1556 (11th Cir. 1983). Three tests are set out in *Pennsylvania v. Nelson* to determine if state law is implicitly pre-empted.

The first test is whether the federal scheme is so pervasive as to make reasonable the inference that Congress left no room for the states to supplement it. *Pennsylvania v. Nelson*, 350 U.S. at 502, 76 S.Ct. at 480, 100 L.Ed. 640. The federal scheme set out in the statutes and implementing regulations at issue here is comprehensive. The three basic requirements of section 351 of the Public Health Service Act ("Act") are that each establishment producing a biological product be licensed, each product be licensed based on standards designed to insure safety, purity, and potency, and that the package and labeling meet specified standards. 42 U.S.C.A. § 262 (1982). Within the federal regulations implementing the Act, 21 C.F.R. §§ 600.3-26 (1983)[3], one part deals specifically with "Source Plasma (Human)," which is defined as the fluid portion of human blood collected by plasmapheresis and intended as source material for further manufacturing use. 21 C.F.R. §§ 640.60-640.76 (1983)[4]. Other portions of

[3] Pursuant to Section 361 of the Act, 42 U.S. C.A. § 264 (1982), and under authority delegated to him, 21 C.F.R. § 5.10, the Commissioner of Food and Drugs is authorized to promulgate regulations. When an administrator promulgates regulations intended to pre-empt state law, the court will not disturb his efforts unless he has exceeded his statutory authority or acted arbitrarily. In examining pre-emption regulations, the court must ask whether the administrator intended to pre-empt state law, and if so, whether that action is within the scope of the administrator's delegated authority. *Fidelity Federal Savings & Loan Association v. De La Cuesta*, 458 U.S. at 151, 102 S.Ct. at 3022, 73 L.Ed.2d 664. In this case, there is no contention that the regulations promulgated pursuant to the Act exceed statutory authority. It does not appear to the Court that the regulations extend beyond the authority granted by Congress.

[4] The regulations prescribe rules as to consent of a prospective donor, medical supervision of the procedure, suitability of donors, method of collection, requirements of the plasmapheresis procedure, immunization of donors, testing for hepatitis, processing of the blood, pooling, inspection, labeling, manufacturing responsibility, records, reporting of fatal donor reactions, modification of source plasma, alternate procedures, and products stored or shipped at unacceptable temperatures.

the regulations implementing the Act also apply to plasmapheresis[5].

The federal regulations are broad in scope and cover virtually every phase of the plasmapheresis process. The pervasiveness of the regulatory scheme makes it reasonable to infer that Congress left no roon for local ordinances to supplement it. *See Howard v. Uniroyal, Inc.*, 719 F.2d 1552 at 1559 (11th Cir. 1983). Nevertheless, pre-emption is not to be inferred merely from the comprehensiveness of the federal scheme. *New York State Department of Social Services v. Dublino*, 413 U.S. 405, 415, 93 S.Ct. 2507, 2514, 37 L.Ed.2d 688 (1973).

The second test under *Pennsylvania v. Nelson* is whether the federal statute touches a field in which the federal interest is so dominant that the federal system must be assumed to preclude enforcement of state laws on the same subject. *Pennsylvania v. Nelson*, 350 U.S. at 504, 76 S.Ct. at 481, 100 L.Ed. 640. Congress has maintained extensive and comprehensive control over the nation's blood collection since 1946. 38 Fed.Reg. 2966 (1973). The collection of blood is an area of national concern, for "[h]uman blood is a priceless resource." 39 Fed.Reg. 18614 (1974). According to the Commissioner of Food and Drugs:

> The promulgation of standards for these biological drugs is part of an existing effort to increase the quality of blood related health care in this country. Pursuant to the findings of a special Task Force in Blood Banking, the Secretary of Health, Education, and Welfare has established a *comprehensive National Blood Policy*. One of the fundamental methods prescribed by the Secretary to implement the policy is to "employ the full regulatory authorities now vested in the Federal Government . . . for the purpose of assuring uniform adherence to the highest attainable standards of practice in blood banking, including plasmapheresis and plasma fractionation."

[5] The subjects included within the remaining regulations are establishment standards and inspection, 21 C.F.R. §§ 600.3-22 (1983); licensing, 21 C.F.R. §§ 601.1-601.33 (1983); good manufacturing practices for blood and blood components, 21 C.F.R. §§ 606.3-606.170 (1983) (with specific sections relating to personnel, facilities, equipment, supplies and reagents, standard operating procedures, finished product and laboratory controls, labeling, records, and reports); establishment registration and product listing, 21 C.F.R. §§ 607.3-607.65 (1983); general biological products standards, 21 C.F.R. §§ 610.65 (1983) (including standards of potency, hepatitis requirements, dating periods, and labeling standards).

39 Fed.Reg. 18614 (1974) (emphasis added). *See also* 39 Fed.Reg. 18615 (1974) ("Such regulations are within the broad Congressional mandate to pursue the high remedial public health purpose of both the Federal Food, Drug and Cosmetic Act and the Public Health Service Act.") Furthermore, the Supreme Court has indicated that the Food, Drug, and Cosmetic Act should be given a liberal construction consistent with its overriding purpose to protect the public health. *See United States v. An Article of Drug ... Bacto-Unidisk ...*, 394 U.S. 784, 798, 89 S.Ct. 1410, 1418, 22 L.Ed.2d 726 (1960); *United States v. Dotterweich*, 320 U.S. 277, 280, 64 S.Ct. 134, 136, 88 L.Ed. 48 (1943).

Although the County possesses an interest in the health of its residents, federal laws may still preclude enforcement of the County scheme. *See Fidelity Federal Savings & Loan Association v. De La Cuesta*, 458 U.S. 141, 151, 102 S.Ct. 3014, 3022, 73 L.Ed.2d 664 (1982) (pre-emption is not inapplicable simply because real property is a matter of special concern to the states). The regulations clearly express a federal interest in establishing a uniform "National Blood Policy." *Cf. Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 143-44, 83 S.Ct. 1210, 1218, 10 L.Ed.2d 248 (1963) (the maturity of avocados is an inherently unlikely candidate for exclusive federal regulation). Therefore, we conclude that the federal interest in plasmapheresis is dominant over any local interest.

The third test in *Pennsylvania v. Nelson* is whether the enforcement of state law presents a serious danger of conflict with the administration of the federal program. 350 U.S. at 505, 76 S.Ct. at 482, 100 L.Ed. 640. The Commissioner of Food and Drugs described the purpose of the federal scheme as follows:

> To insure there is a continued healthy donor population to serve as a source of plasma to be used in the manufacture, by the fractionation technique, of safe, pure, and potent blood products, the Commissioner is including in these proposed additional standards for Source Plasma (Human) specific provisions designed to protect the health and well-being of the donor.

37 Fed.Reg. 17420 (1972). Thus, the regulations were designed to protect the plasma donors, to insure that the product is safe, and to insure the continued existence of a healthy donor population. *See also* 39 Fed.Reg. 26162 (1974); 39 Fed.Reg. 18615 (1974); 41 Fed.Reg. 10762-63 (1976). The regulations were also

enacted to establish uniform standards for blood banking. 39 Fed.Reg. 26161 (1974). The goal of uniformity runs throughout the regulations. *See, e.g.*, 48 Fed.Reg. 26313 (1983) (one reason for regulations establishing FDA inspection at least once every two years is to provide uniformity in the frequency of inspection).

The purpose of the County scheme is similar to that of the federal scheme. Section 15 of Ordinance 80-12 incorporates by reference the federal regulations appearing at 21 C.F.R. Part 640, Subpart G, Section 640.60 *et seq*. As noted earlier, these are the provisions of the federal regulatory scheme relating solely to "Source Plasma (Human)." The other provisions of the County Ordinances, however, impose additional requirements on plasmapheresis centers.[6]

These additional County requirements cover areas that are clearly encompassed by the federal regulations. Unlike *Smith v. Pingree*, 651 F.2d 1021, 1025 (5th Cir. 1981) (Unit B), in which the court found that the federal requirements did not regulate every aspect of the area and so the state had the implied reservation to fill out the scheme, the federal scheme here regulates every aspect of plasmapheresis. The County scheme imposes burdensome and expensive requirements in addition to the requirements of the comprehensive federal scheme. If the County scheme remains in effect, the national blood policy of promoting uniformity and guaranteeing a continued supply of healthy donors will be adversely affected. *See Campbell v. Hussey*, 368 U.S. 297, 301, 82 S.Ct. 327, 329, 7 L.Ed.2d 299 (1961) (pre-emption found where act refers to need for uniform official standards); *Howard v. Uniroyal*, 719 F.2d 1552 at 1560 (11th Cir. 1983) (pre-emption found where one of Congress's objectives was to insure that there would be a uniform, consistent federal approach).

Thus, Automated has satisfied the three tests set out in *Pennsylvania v. Nelson*. This Court holds that Hillsborough Coun-

[6] The County scheme adds the following requirements: 1) A person may donate plasma only after obtaining a donor registration card, at a cost of $2.00, valid for six months at a single designated plasma center; 2) a donor registration card is issued only after the donor receives a complete physical exam and a hepatitis test and presents a sworn statement that within the preceding year, he or she has not been treated for chronic or acute alcoholism; 3) the plasma center must keep and forward daily to the Department records of the donors and procedures performed; 4) each donor must undergo a breath analysis prior to donation; 5) the Department shall inspect the plasma center at least once a year, and 6) the plasma center must pay the Department $1.00 for each plasmapheresis procedure performed.

ty Ordinances 80-11 and 80-12 and the implementing rules and regulations are pre-empted by the federal scheme. The Court need not reach any other issues raised on appeal. Accordingly, the judgment of the district court finding Section 7 of Ordinance 80-12 and § 4 of the rules and regulations invalid is AFFIRMED, the judgment finding the remaining sections of the County Ordinances and implementing rules and regulations valid is REVERSED.

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

Case No. 81-1161-Civ-T-WC

AUTOMATED MEDICAL LABORATORIES, INC.,
Plaintiffs,
vs.
HILLSBOROUGH COUNTY, FLORIDA, et al.,
Defendants.

FILED CLERK, U.S. DISTRICT COURT
NOV. 1, 1982
MIDDLE DISTRICT OF FLORIDA, TAMPA, FLORIDA

OPINION

This cause came on before the Court on a non-jury trial on September 16 and 17, 1982. Plaintiff Automated Medical Laboratories, Inc. filed this action against Hillsborough County, Florida and the Hillsborough County Health Department, challenging the constitutionality of Hillsborough County Ordinances 80-11 and 80-12 and the Rules and Regulations promulgated thereunder. The challenged ordinances regulate licensing and operation of paid blood plasma donor centers. Plaintiff sought a declaratory judgment that the ordinances were unlawful and a permanent injunction against enforcement of the legislation.

Plaintiff challenged the ordinances on several grounds. It claimed that federal legislation preempted the local laws, that the local ordinances impermissibly burdened interstate commerce, and that the county ordinances unlawfully deprived Plaintiff of equal protection of the law by regulating only plasma centers that pay donors and not centers where unpaid volunteers donate whole blood. Plaintiff raised several other issues in the pleadings, such as unlawful delegation, violation of rights, privileges and immunities, and violation of due process. Plaintiff did not specifically adduce evidence or address these issues at trial, however, and the Court finds these arguments without merit.

Based on the evidence presented at trial and a review of the exhibits, the Court makes the following findings:

(1) Plaintiff is a Florida corporation that operates, through subsidiary corporations, eight blood plasma centers in the United States, one of which, Tampa Plasma Corporation, is located in Tampa, Hillsborough County, Florida. Plaintiff's plasma centers collect blood plasma from paid donors by plasmapheresis. In a single procedure this process removes whole blood from the donor, removes the plasma from the whole blood, and then returns the red blood cells to the donor. Plaintiff sells the plasma collected to pharmaceutical concerns that manufacture it as a raw material into products such as tetanus vaccine, albumin, and anti-hemophilic factor. Tampa Plasma Corporation collects and sells no whole blood.

(2) When Hillsborough County enacted the challenged ordinances, the Food and Drug Administration of the United States Department of Health and Human Services had issued regulations in 21 C.F.R. Subchapter F - Biologics that established standards and procedures for plasmapheresis operations. The regulations provide for FDA inspection of plasmapheresis facilities, establish standards for personnel and physical plants, necessitate licenses for plasmapheresis products and facilities, and establish human blood product standards, including the means to select suitable plasmapheresis donors.

(3) Hillsborough County Ordinance 80-11 imposes a license fee on plasmapheresis centers. The purpose of Hillsborough County Ordinance 80-12 is "to provide a system for the registration and identification of and the gathering of medical data applicable to Commercial Blood Plasma Vendors as being in the common interest of the health of the people of Hillsborough County." Pertinent provisions include the requirement that all plasma vendors obtain an identification card from the Health Department (at a cost of $2.00 as provided for in the rules and regulations pursuant to the ordinance). The ordinance requires the plasmapheresis centers to keep records of the procedures they perform, including the results of hepatitis testing, and to ascertain that a plasma vendor has not undergone a plasmapheresis procedure within specified time periods. The ordinance prohibits performance of the plasmapheresis procedure on any vendor who has not obtained a certificate of good health after examination by a physician. It imposes a fee, not to exceed $1.00, for each procedure performed, with a limitation that fees collected shall not exceed the cost of administering and maintaining the identification system. It requires a pre-plasmapheresis breath analysis of each vendor by means of approved equipment, material, and supplies. The ordinance incorporates

by reference the FDA regulations as they appear at 21 C.F.R., Subpart G, Section 640.60 et seq.

(4) In conformance with the FDA Regulations, Tampa Plasma Center currently provides its donors with identification cards. These cards are issued by individual centers, however, and plasma centers throughout the county do not cross-check with each other to ascertain whether a vendor has recently undergone plasmapheresis. The prospective vendor must give a medical history and undergo a physical examination, parts of which are performed by the center's non-medical personnel. A physician who has informed the vendor of the possible hazards and has questioned him about his understanding of the procedure accepts or rejects the vendor. After the plasmapheresis procedure is completed, a hepatitis test is performed and the plasma is kept in segregated storage until the center receives the results.

Under the county ordinances, the vendor would be required to obtain a county-wide identification card, which would not be issued prior to performance of a physical exam. The vendor would undergo a hepatitis test prior to registration, and breath analysis for alcohol content would be performed prior to each plasma donation.

(5) At trial, officers of the Plaintiff corporation attempted to establish the cost to Plaintiff of compliance with the ordinances. Their figures, however, were clouded with speculation. Mr. Dennis Healey, for instance, testified about a document he prepared (Exhibit 20) showing estimates of implementation costs. Except for the cost of the new fees, implemented by the Hillsborough County Health Department, the other estimated increased costs were based on Mr. Healey's opinion that the vendor population would decrease by twenty-five percent once the ordinances were enforced, primarily because the cost and inconvenience of obtaining the Health Department identification card would discourage new vendors. Mr. Healey, however, testified to no facts on which he based his opinion.

Plaintiff also encountered difficulty in estimating the increased cost per liter of plasma attributable to the requirement that the plasmapheresis center determine a prospective vendor's blood alcohol content by use of breathalyzer equipment manned by personnel with approved training. Plaintiff estimated that the machine alone would cost about $5,000.00; however, personnel training costs could not be estimated because approved training

presently is available only through the Tampa Police Department.

(6) Much of the testimony at trial concerned the intent of the County Commissioners in enacting the ordinances. Plaintiff attempted to demonstrate that the ordinances were enacted in response to the social problems caused by inebriates and vagrants frequenting the area around the plasma centers. Plaintiff argued that the purpose of the regulations was to eliminate plasmapheresis centers from Hillsborough County by imposing severe economic burdens on their operations. Plaintiff failed to prove, however, that the legislative intent was anything other than that articulated in Ordinance 80-12 — to register and to identify vendors and to supplement and extend the federal regulations and their purposes.

(7) Defendants introduced testimony from physicians qualified as experts in the plasmapheresis field as to the need for and beneficial effect of a county-wide system of vendor identification. Under the federal regulations no system monitors the frequency with which individual vendors undergo the plasmapheresis procedure. Because of monetary inducements for undergoing plasmapheresis, vendors may donate plasma too frequently and put themselves in real danger of being overbled. This problem is particularly acute when the vendor is a chronic alcoholic with borderline liver function. The donor identification system will also help to insure the quality of the product in that vendors will be screened for hepatitis before they receive their identification cards, thus eliminating the hazards involved in handling potentially contaminated plasma.

Defendants' medical experts also expressed concern that a vendor under the influence of alcohol may not have sufficient understanding of the nature of the procedure and the risks it entails. The breathalyzer test requirement is intended to solve this problem. Under the federal regulations, however, Automated Laboratories, Inc. has established reliable procedures to screen out persons under the influence of alcohol at two stages — when they are initially tested by the receptionist and when the physician examines them.

(8) The ordinances in question regulate only plasmapheresis centers that pay vendors. Testimony at trial showed that no whole blood centers in Hillsborough County pay donors. Furthermore, the legislators' concern for the safety of

vendors and the quality of the product is applicable only to paid centers. Medical experts testified that plasma vendors have a much higher incidence of hepatitis than voluntary whole blood donors. Also, the problem of overbleeding does not exist among voluntary whole blood donors who have no monetary incentive to make frequent donations.

Based on the foregoing findings of fact the Court makes the following conclusions of law:

(1) Hillsborough County Ordinances 80-11 and 80-12 and the rules and regulations promulgated thereunder are not preempted by federal regulation. "There is neither such actual conflict between the two schemes of regulation that both cannot stand in the same area, nor evidence of a congressional design to preempt the field." *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 141 (1963). Plaintiff pointed to language in the Federal Register expressing the purpose of the federal regulations "to assure uniform adherence to the highest attainable standards of of practice in blood banking, including plasmapheresis and plasma fractionation," 39 Fed.Reg. 18614 (1974); but there is no evidence of express congressional intent to occupy the entire field of assuring high standards of practice in plasmapheresis. Moreover, the comprehensive nature of the federal legislation alone does not imply a congressional intent to preempt. *New York State Dep't. of Social Servs. v. Dublino*, 413 U.S. 405, 415 (1973). Finally, Hillsborough County Ordinances 80-11 and 80-12 supplement rather than conflict with the federal regulations, particularly in the ordinances' emphasis on ensuring vendor safety.

(2) Hillsborough County Ordinances 80-11 and 80-12 and the rules and regulations promulgated thereunder do not deprive Plaintiff of equal protection of the laws. Although the local legislation applies only to paid plasmapheresis centers and not to voluntary whole blood centers, Defendants successfully demonstrated that there is a rational basis for regulating only the paid plasma centers. Because Plaintiff contends that the ordinances deprive Plaintiff of a property right rather than infringe upon a fundamental personal right, a rational basis for enactment of the statute is sufficient. *New Orleans v. Dukes*, 427 U.S. 297 (1976). This rational basis is evident from the following: vendors tend to sell their plasma more frequently than volunteers donate their whole blood; plasma vendors have a much higher rate of hepatitis than whole blood donors; and no paid whole blood centers exist in Hillsborough County.

(3) Hillsborough County Ordinance 80-11 and the rules and regulations promulgated thereunder do not place an impermissible burden on interstate commerce. Section 7 of Hillsborough County Ordinance 80-12 and Section 4 of the Rules and Regulations Pursuant to Hillsborough County Ordinance 80-12 impermissibly burden interstate commerce. The remainder of Hillsborough County Ordinance 80-12 and the Rules and Regulations Pursuant to Hillsborough County Ordinance 80-12 do not place an impermissible burden on interstate commerce.

The Supreme Court has stated the general rule for determining whether a state or local law is invalid by virtue of its effect on interstate commerce:

> Where the statute regulates evenhandedly to effect a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to putative public benefits. If a legitimate local purpose is found, then the question becomes one of degree. And the extent of the burden that will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities.

Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970).

For reasons previously stated, the Court finds that the ordinances regulate evenhandedly and serve a legitimate local purpose. The Court must therefore determine whether the burden, if any, imposed on interstate commerce is clearly excessive in relation to local benefits.

The Plaintiff was unable to demonstrate the total economic impact on it of enforcement of the ordinances. The evidence demonstrated, however, that significant protection for vendors would be assured by the vendor identification system, that the hepatitis pre-test requirement will help insure the quality of the product, and that the license and plasmapheresis fees will pay for the cost to the County of implementing and enforcing the ordinances. Clearly, all of these provisions, which will create some economic burden on the Plaintiff, will significantly benefit the health, safety, and welfare of the citizens of Hillsborough County.

The benefits of the breathalyzer requirement are not so readily apparent, however. Plaintiff demonstrated that the procedures it follows under the federal regulations achieved the same purpose as a breathalyzer test though the subjective evaluation of each potential vendor by the Plaintiff's personnel and physicians. Defendants did not demonstrate that the breathalyzer requirement, which will create a large, albeit precisely undedetermined, economic burden on the Plaintiff, will "effectuate a legitimate public interest" that is not already achieved by Plaintiff's requirement with the federal regulations. Therefore, Section 7 of Hillsborough County Ordinance 80-12 and Section 4 of the Rules and Regulations Pursuant to Hillsborough County Ordinance 80-12 are invalid in that they impose an impermissible burden on interstate commerce.

Judgment will be entered in accordance with this Opinion.

DATED at Tampa, Florida this 1st day of November, 1982.

WILLIAM J. CASTAGNA
UNITED STATES DISTRICT JUDGE

Copies to:

Counsel of Record

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

Case No. 81-1161-Civ-T-WC

AUTOMATED MEDICAL LABORATORIES, INC.,
Plaintiffs,
vs.
HILLSBOROUGH COUNTY, FLORIDA, et al.,
Defendants.

FILED CLERK, U.S. DISTRICT COURT
NOV. 1, 1982
MIDDLE DISTRICT OF FLORIDA, TAMPA, FLORIDA

FINAL JUDGMENT

In accordance with the Opinion filed herein this date, it is

ADJUDGED:

Section 7 of Hillsborough County Ordinance 80-12 and Section 4 of the Rules and Regulations Pursuant to Hillsborough County Ordinance 80-12 are invalid in that they impose an impermissible burden on interstate commerce and the Defendants and their agents and employees are hereby enjoined from enforcing or attempting to enforce them.

As to the other claims of Plaintiff Automated Medical Laboratories, Inc., Judgment is entered in favor of the Defendants Hillsborough County, Florida and Hillsborough County Health Department, and Plaintiff shall take nothing.

DATED at Tampa, Florida this 1st day of November, 1982.

WILLIAM J. CASTAGNA
UNITED STATES DISTRICT JUDGE

Copies to:

Counsel of Record

United States Court of Appeals
FOR THE ELEVENTH CIRCUIT

NO. 83-3014

D.C. Docket No. 81-1161-WC
AUTOMATED MEDICAL LABORATORIES, INC.,
Plaintiff-Appellant,

versus
HILLSBOROUGH COUNTY, FLORIDA, and
HILLSBOROUGH COUNTY HEALTH DEPARTMENT,
Defendants-Appellees.

Appeal from the United States District Court for the
Middle District of Florida

Before FAY and HENDERSON, Circuit Judges, and TUTTLE, Senior Circuit Judge.

J U D G M E N T

This cause came on to be heard on the transcript of the record from the United States District Court for the Middle District of Florida, and was argued by counsel;

ON CONSIDERATION WHEREOF, it is now here ordered and holding adjudged by this Court that the judgment of the District Court finding Section 7 of Ordinance 80-12 and § 4 of the rules and regulations invalid is AFFIRMED; the judgment finding the remaining sections of County Ordinances 80-11 and 80-12 and implementing rules and regulations valid is REVERSED;

It is further ordered that defendants-appellees pay to plaintiff-appellant, the costs on appeal to be taxed by the Clerk of this Court.

ISSUED AS MANDATE: MAR 8- 1984

Entered: January 16, 1984
For the Court: Spencer D. Mercer, Clerk
BY: _____
Deputy Clerk

PETITION FOR REHEARING BY PANEL

EMELINE C. ACTON
DOLORES D. MENENDEZ
Assistant County Attorneys
Hillsborough County, Florida
Post Office Box 1110
Tampa, Florida 33601
Telephone: (813) 272-5670

ARGUMENT

Petitioner respectfully requests a rehearing by this court on the issue of whether the challenged local legislation is preempted by the federal regulations concerning plasma. In support of this request, Petitioner asserts that this preemption issue was initially raised in the *amicus* brief. Petitioner was unable to respond to this new issue raised in the *amicus* brief because Petitioner's/Appellee's Answer had already been filed. Moreover, Petitioner had specificially requested the opportunity to respond to the new issues raised by the *amicus* brief in its Motion for Rehearing or Clarification filed July 8, 1983. That opportunity to respond was denied by the court in its Order filed on August 1, 1983, even though Fed. R. App. P. 29 provides as follows: "Save as all parties otherwise consent, any *amicus* brief will support *unless the Court for cause shown shall grant leave for later filing, in which event it shall specify within what period an opposing party may answer*". (Emphasis supplied.)

Because the court's opinion of January 16, 1984 strikes down the local legislation solely on the grounds that the federal government had implicitly preempted the field of plasma regulation, petitioner respectfully requests a rehearing so that the court may re-examine its opinion with full knowledge of evidence and argument on this issue.

The court held that the local legislation was preempted by the federal plasma regulations despite the absence of an express intent to preempt and despite the fact that preemption cannot be presumed in the absence of such a provision. *New York State Dept. of Social Services v. Dublino*, 413 U.S. 405 (1973). Where no express preemption or conflict exists, state and federal legislation must be examined to determine whether they can coexist. Federal and local enactments should as a rule be accommodated and the law does not favor the outster of local legislation. *Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Ware*, 414 U.S. 117 (1973). Despite this general rule, the court struck down this local legislation and effectively barred local regulation in this field.

Moreover, the court based its decision on the holding in *Pennsylvania v. Nelson*, 350 U.S. 497 (1956), in which the Supreme Court ruled that the area of sedition legislation had been implicitly preempted by the federal government. In applying the Nelson rationale to the facts in the instant case, however, the court overlooked the fact that sedition has long been recognized as a subject of peculiarly national concern. In fact, the *Nelson* court noted that acts of sedition are acts that are contrary to the interests of the United States and threaten the national security. Furthermore, the court emphasized that the President of the United States had specifically instructed all law enforcement personnel to turn over to the Federal Bureau of Investigation any information in their possession relating to seditious acts. The court also drew attention to the fact that

other federal officials had similarly spoken to the necessity for exclusively federal control of seditious acts against the United States.

On the other hand, the area of public health has long been recognized by the courts as one of particularly local concern.[1] As opposed to the federal officials in the *Nelson* case who spoke out in favor of solely federal control, the Food and Drug Administration stated that it was "pleased to cooperate with Hillsborough County in matters directed at improving consumer protection" and gave consent for Edward R. Atkins, Director of Compliance for the State of Florida, and Herbert M. Smith, Resident in Charge, Tampa Resident Post, to testify on behalf of the local legislation. In regard to the protections supplied by the local legislation which the federal regulations did not cover, Mr. Atkins and Mr. Smith specifically testified that any additional inspection of the plasma firms would be helpful and that such local enforcement would create no difficulties for Mr. Atkins' office in carrying out its duties of regulating plasma centers. (TR 215-216, 223-225)

Furthermore, although the court quotes on page 1251 of its opinion from the Commissioner of Food and Drugs who established a comprehensive National Blood Policy based upon the findings of a special Task Force in Blood Banking, the court overlooks the testimony of Drs. Schmidt and Coleman who were members of that same Task Force on Blood Banking which had advised the federal government on appropriate regulations in this field. (TR 179-180, 200) They testified that the Task Force's recommendation of a uniform vendor registration system for use among several different centers in an area in order to protect the health of vendors had not been incorporated into the federal regulations but was included in the local legislation. (TR 183, 198-200) This evidence that the federal plasma regulations do not encompass all possible areas for the protection of the public health supports the Petitioner's contention that the Commissioner's call for "uniform adherence to the highest attainable standards" was not an announcement of preemption.

[1]Local legislation which seeks to protect the physical health and safety of those persons within its territory is "most impervious to preemption." A Framework for Preemption Analysis, 88 *Yale L.J.* 363, 374 (1978). Thus, the Supreme Court has upheld: 1) local legislation that imposed a requirement that a national agency had refused to impose, *Maurer v. Hamilton*, 309 U.S. 598 (1940), 2) state regulation of the same action regulated by a national agency but for the violation of which the state imposed higher penalties, *California v. Zook*, 336 U.S. 725 (1949), 3) a municipal ordinance regulating a local health concern caused by steam vessels which were already in compliance with comprehensive federal regulations, *Huron Portland Cement Co. v. City of Detroit, Michigan*, 363 U.S. 440 (1960) and 4) state regulation prohibiting the transportation or sale of certain avocados within California which avocados were already marketable under stringent federal standards, *Florida Lime and Avocado Growers, Inc. v. Paul*, 373 U.S. 132 (1963).

Rather, the Commissioner was calling for the highest standards which the federal government was able to effectively enforce. These federal standards constitute a minimum level of public health protection beyond which local governments may impose additional reasonable standards. This is particularly true in regard to the challenged local legislation in that this legislation sought to protect aspects of the public health not covered by the federal regulations such as excessive bleeding through visits to different plasma centers, subjective tests of intoxication of prospective vendors performed by employees who benefit depending upon their findings, and exposure in centers to hepatitis positive vendors. Thus, although the court on page 1251 of its opinion distinguishes the local legislation which was upheld in *Smith v. Pingree*, 651 F.2d 1021 (5th Cir. 1981) (Unit B), the federal requirements in both the *Smith* case and the instant case do not regulate every aspect of those areas and leave room for the local legislation to fill out the scheme.

The court's decisive reliance on *Pennsylvania v. Nelson* was misplaced. Rather, the court should have applied the principle enunciated by the United States Supreme Court in the landmark case of *Florida Lime* at 142 that "Federal regulation of a field of commerce should not be deemed preemptive of state regulatory power in the absence of persuasive reasons — either that the nature of the regulated subject matter permits no other conclusion or that the Congress has inmistakenly so ordained." Although plasma is an admittedly important product, the regulation of the plasma industry is a commercial regulation as opposed to regulation for the national security and federal preemption should not be imposed absent persuasive reasons.

Based on the foregoing argument, Petitioner respectfully requests that this court rehear its decision in this case.

Respectfully submitted this 3rd day of February, 1984.

EMELINE C. ACTON

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that copies of the foregoing Petition for Rehearing has been furnished by U.S. Mail this 3rd day of February, 1984 to: Richard Landfield, Attorney for American Blood Resources Association and Florida Association for Plasmapheresis Establishments, 1220 Nineteenth Street, N.W., Suite 205, Washington, D.C. 20036, and Larry A. Stumpf, Attorney for Automated, Goldstein, Goldman, Kessler & Underberg, 2606 New Work Tower, 100 North Biscayne Boulevard, Miami, Florida 33132.

EMELINE C. ACTON

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

U.S. COURT OF APPEALS
ELEVENTH CIRCUIT
FILED
FEB 23 1984
Spencer D. Mercer
Clerk

NO. 83-3014

AUTOMATED MEDICAL LABORATORIES, INC.,
Plaintiff-Appellant,

versus

HILLSBOROUGH COUNTY, FLORIDA, and
HILLSBOROUGH COUNTY HEALTH DEPARTMENT,
Defendants-Appellees.

Appeal from the United States District Court for the
Middle District of Florida

ON PETITION FOR REHEARING

(FEB 23 1984)

Before FAY and HENDERSON, Circuit Judges, and TUTTLE, Senior Circuit Judge.

PER CURIAM:

IT IS ORDERED that the petition for rehearing filed in the above entitled and numbered cause be and the same is hereby denied.

ENTERED FOR THE COURT:

United States Circuit Judge

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

U.S. COURT OF APPEALS
ELEVENTH CIRCUIT
FILED
APR 20 1984
Spencer D. Mercer
Clerk

AUTOMATED MEDICAL LABORATORIES, INC., :
Plaintiff-Appellant, :
-vs- : CASE NO. 83-3014
HILLSBOROUGH COUNTY, FLORIDA, and :
HILLSBOROUGH COUNTY HEALTH DEPARTMENT, :
Defendants-Appellees. :

NOTICE OF APPEAL

Appellant, HILLSBOROUGH COUNTY, FLORIDA, appeals from the Order entered on February 23, 1984 by the United States Court of Appeals, Eleventh Circuit, which denie a rehearing of its decision holding that the federal government had preempted the area of plasma legislation and therefore striking down the ordina es and regulations enacted by HILLSBOROUGH COUNTY to regulate the collection of plasma. This appeal to the United States Supreme Court is taken pursuant to 28 *U.S.C.* §1254(2).

EMELINE C. ACTON
DOLORES D. MENENDEZ
Assistant County Attorneys
Members, United States
Court of Appeals for The
Eleventh Circuit Bar
Post Office Box 33601
Tampa, Florida 33601
(813) 272-5670

DOUGLAS R. GARDNER
Assistant County Attorney
Member, United States
Supreme Court Bar
Post Office Box 1110
Tampa, Florida 33601
(813) 272-5670

CERTIFICATE OF SERVICE

All parties required to be served have been served by depositing on this 19th day of April, 1984 copies of this document in a U.S. Post Office, with first class postage prepaid, addressed to counsel of record at his or her post office address as follows:

Richard Landfield, Esq.
Attorney for American Blood Resources and
Florida Association for Plasmapheresis
Establishments
1220 Nineteenth Street, N.W., Suite 205
Washington, D.C. 20036

Larry A. Stumpf, Esq.
Attorney for Automated
Suite 1000 Flagship Center
777 Brickell Avenue
Miami, Florida 33131

Amelia M. Park, Esq.
Attorney for Hillsborough County Health
Department
Health & Rehabilitative Services
4000 W. Buffalo Avenue
Tampa, Florida 33614

EMELIN C. ACTON
DOLORES D. MENENDEZ

DOUGLAS R. GARDNER

MLZ
11/26/80

ORDINANCE #80-11

AN ORDINANCE AMENDING THE HILLSBOROUGH COUNTY OCCUPATIONAL LICENSE ORDINANCE #80-6; PROVIDING A SPECIFIC CLASSIFICATION FOR BLOOD PLASMA DONOR CENTERS AND SETTING THE OCCUPATIONAL LICENSE TAX AT $225.00; PROVIDING FOR A PERMIT, AND PROVIDING AN EFFECTIVE DATE

Section 1. Hillsborough County Ordinance 80-6 is amended to add Section 56.01 to read as follows:

Section 56.01 BLOOD PLASMA DONOR CENTERS

(1) Every person or association of persons conducting, carrying on or otherwise engaging in the business (occupation) of a Blood Plasma Donor Center as defined below, shall pay a license tax of $225.00.

(2) "Blood Plasma Donor Center" is defined as any facility, laboratory, or place of business which performs the procedure known as "plasmapheresis" on commercial Blood Plasma Vendors and which compensates said Blood Plasma Vendors by payment of money or other thing of value.

Section 2. Hillsborough County Ordinance 80-6 is amended to add Section 57.01 to read as follows:

Secton 57.01 — BLOOD PLASMA DONOR CENTERS; COUNTY PERMIT REQUIRED; PENALTY —

(1) No license to engage in the occupation of a Blood Plasma Donor Center or any other business entity for which a license is required by Section 56.01 of this Ordinance, shall be issued to any person or association of persons not possessing a valid permit issued by the Hillsborough County Board of County Commissioners (Board). Said permit shall be issued in triplicate with the original being given to the applicant, one copy being retained by the Hillsborough County Health Department, and one copy being retained by the Tax Collector. All permits and licenses issued under the provisions of this Ordinance shall be non-transferable. No permit shall be issued by the Board until the following conditions have been fulfilled:

(a) The applicant for the permit has:

1. Furnished the Hillsborough County Health Department (upon forms provided) with the name and mailing and residential addresses for all non-owner and owner personnel employed with the place of business for which the related license tax is applicable pursuant to Section 56.01 of this Ordinance.

2. Furnished to the Hillsborough County Health

Department (upon forms provided) a list and description of the equipment and facilities of the place of business for which related license tax is applicable pursuant to Section 56.01 of this Ordinance.

3. Furnished to the Hillsborough County Health Department (upon forms provided) such other information as deemed necessary by the Hillsborough County Health Department.

4. Allowed the Hillsborough County Health Department reasonable and continuing access to the premises of the Blood Plasma Donor Center or other business entity concerned with the permit sought by the applicant; said access being granted for purposes of allowing the Hillsborough County Health Department opportunity to inspect the premises.

(2) The possessor of any permit issued by the Board shall, within thirty (30) days of an event or occurrence that causes a change to the information given to the Hillsborough County Health Department pursuant to sub-sections 57.01(1)(a)1, 57.01(1)(a)2, and 57.01(1)(a)3 of this Ordinance, advise the Hillsborough County Health Department (in writing) of such change.

(3) The Hillsborough County Health Department shall, within fifteen (15) days of receiving a completed application for a permit as described by this Section, forward to the Board all such information furnished by the permit applicant; together with the recommendation of the Hillsborough County Health Department and other pertinent information deemed advisable. The Board shall consider the information submitted to it in open, public meeting after notice to the permit applicant and the Hillsborough County Health Department; whereupon the Board shall either issue the permit, continue the matter for just cause, or deny the permit.

(4) Blood Plasma Donor Centers or other business entities issued a permit pursuant to the provisions of this Section shall automatically be re-permitted annually by the Board unless such re-permitting is denied by the Board for just cause after notice and opportunity to be heard. The County Tax Collector shall be notified when re-permitting is denied by the Board.

(5) Every licensee comprehended by Section 56.01 of this Ordinance shall at all times while engaging in the occupation for which licensed, display at the applicable place of business both the license thereby required and the permit required by this Section. Failure or refusal to do so shall be prima facie evidence of engaging in such occupation without a license.

(6) Anyone engaging in any occupation comprehended by

Section 56.01 of this Ordinance without a license and the permit required by this Section or who shall obtain any such permit or license by fraud or deceit shall, be subject to prosecution and punishment as described in Section 7.02 of this Ordinance.

Section 3. This Ordinance shall become effective immediately upon acknowledgement from the Secretary of State that it has been properly filed as required by law.

STATE OF FLORIDA)
COUNTY OF HILLSBOROUGH)

I, JAMES F. TAYLOR, Clerk of the Circuit Court and Ex Officio Clerk of the Board of County Commissioners of Hillsborough County, Florida, do hereby certify that the above and foregoing is a true and correct copy of an Ordinance adopted by the Board in its regular meeting of November 26, 1980, as the same appears of record in Minute Book 76 of the Public Records of Hillsborough County, Florida.

WITNESS my hand and official seal this 5th day of December, 1980.

JAMES F. TAYLOR, JR., CLERK
BY: _____
Deputy Clerk

FINAL
MLZ
11/26/80

ORDINANCE #80-12

AN ORDINANCE OF HILLSBOROUGH COUNTY, FLORIDA; RELATING TO IDENTIFICATION OF COMMERCIAL BLOOD PLASMA VENDORS: DEFINING TERMS; REQUIRING BLOOD PLASMA VENDOR IDENTIFICATION CARDS; ESTABLISHING PROCEDURES FOR OBTAINING CARDS; PROVIDING FOR RECORD KEEPING AND REPORTING; SETTING FEES; REQUIRING BREATH ANALYSIS; REQUIRING REPORTING OF COMMUNICABLE DISEASE; PROVIDING FOR ADMINISTRATION; PROVIDING FOR ENFORCEMENT AND INSPECTION; REQUIRING NOTICE; SPECIFYING PENALTY FOR VIOLATIONS; PROVIDING FOR SEVERABILITY; PROVIDING AN EFFECTIVE DATE.

WHEREAS, Section 125.01(1)(w), Florida Statutes allows the Board of County Commissioners of Hillsborough County, Florida, to perform any acts not inconsistent with law which are in the common interest of the people of the County, and exercise all powers and privileges not specifically prohibited by law; and

WHEREAS, Section 125.01(1)(t), Florida Statutes allows the Board of County Commissioners of Hillsborough County, Florida to adopt ordinances necessary for the exercise of its power; and

WHEREAS, the Hillsborough County Board of County Commissioners finds and determines that the interests of the public health mandate the monitoring of the plasmapheresis procedure within Hillsborough County; and

WHEREAS, Section 381.311, Florida Statutes requires local health officials to enforce provisions of local ordinance relating to the public health.

NOW, THEREFORE, BE IT ORDAINED BY THE BOARD OF COUNTY COMMISSIONERS OF HILLSBOROUGH COUNTY, FLORIDA, IN REGULAR MEETING ASSEMBLED THIS _____ DAY OF _____, 1980.

Section 1. Short Title — This ordinance shall be known as the "Commercial Blood Plasma Vendor Identification Ordinance".

Section 2. Statement of Purpose — The purpose of this Ordinance is to provide a system for the registration and identification of and the gathering of medical data applicable to Commercial Blood Plasma Vendors as being in the common interest

of the health of the people of Hillsborough County.

Section 3. Definitions

(A) "Commercial Blood Plasma Vendor" is defined as an individual who sells, barters, or exchanges for monetary consideration, the liquid portion of his or her blood (plasma), through the plasmapheresis process.

(B) "Plasmapheresis" is defined as the procedure whereby whole blood is removed from a Commercial Blood Plasma Vendor by venipuncture (or phlebotomy) the plasma is separated therefrom, and the blood cells returned to the Vendor.

(C) "Plasmapheresis Facility" is defined as any facility, laboratory, or place of business where Commercial Blood Plasma Vendors participate in the plasmapheresis process.

(D) "Department" is defined as the Hillsborough County Health Department.

Section 4. Plasma Donor Identification Card. All Commercial Blood Plasma Vendors within Hillsborough County are required to obtain a valid plasma vendor identification card from the Department. The card shall contain identifying information, as required by the Department, and a number, unique to the Vendor. Only one (1) card and one (1) number shall be issued to each Vendor. The identification card shall be good for one (1) plasmapheresis facility only, the name of which shall appear on the face of the identification card.

Section 5. Procedure

(A) Each prospective Commercial Blood Plasma Vendor shall, before undergoing plasmapheresis, make application to the Department, on a form to be provided by the Department, for a plasma vendor identification number and a plasma vendor identification card. The Commercial Blood Plasma Vendor must provide such identifying information as is deemed necessary by the Department and shall tender to the Department a fee of no more than ten dollars ($10.00) which fee shall fairly reflect the Department's costs for issuance of the plasma vendor identification card. Identification cards issued under the provisions of this Ordinance shall be valid for six (6) months from the date of issue.

(B) In the event a plasma vendor identification card is lost, stolen, or mutilated, a duplicate card will be issued, which card shall be valid for the same period as the original card, and shall only be good for the same plasmapheresis facility as the original card. The fee for such duplicate shall be no more than three dollars ($3.00).

Section 6. Record-keeping

(A) No plasmapheresis facility within Hillsborough County may perform the plasmapheresis process on a Commercial

Blood Plasma Vendor until said Vendor presents the plasmapheresis facility with a valid plasma Vendor identification card as required by Section 4 of this Ordinance. The plasmapheresis facility shall keep accurate records of each plasmapheresis procedure performed by it, which shall include:

(1) The date of the plasmapheresis procedure;
(2) The name, address, age, weight, height and sex of the Vendor;
(3) The plasma Vendor identification number of the Vendor;
(4) The results of breath analysis of the Vendor as required by Section 7 of this Ordinance;
(5) The amount of whole blood, not including anticoagulant, removed from the Vendor during the plasmapheresis procedure;
(6) The proportion of the blood cells successfully returned to the Vendor at the time of each procedure;
(7) The results of testing for hepatitis;
(8) The current hematocrit value
(9) Any other identifying information as the Department may deem necessary.

(B) All plasmapheresis facilities within Hillsborough County shall provide the aforementioned information daily to the Department, in writing, who shall compile and maintain such information and give prompt notification of any violation of this Ordinance or of the rules and regulations promulgated hereto.

(C) Prior to beginning the plasmapheresis procedure upon any Commercial Blood Plasma Vendor, the plasmapheresis facility shall ascertain that said Vendor has not participated in the plasmapheresis procedure in excess of the amounts listed below within the times indicated:

(1) The amount of whole blood, not including anticoagulant, removed from a Vendor during the plasmapheresis procedure in any forty-eight (48) hour period shall not exceed one thousand (1,000) milliliters unless the Vendor's weight is one hundred seventy-five (175) pounds or greater, in which case the amount of whole blood, not including anticoagulant removed from the Vendor during the plasmapheresis procedure, in any forty-eight (48) hour period shall not exceed one thousand two hundred (1,200) milliliters.

(2) The amount of whole blood, not including anticoagulant, removed from a Vendor during the plasmapheresis procedure, within a seven-day period shall not exceed two thousand (2,000) milliliters, unless the Vendor's weight is one hundred seventy-five (175) pounds or greater, in which case the amount of whole blood, not including anticoagulant, removed from the Vendor during the plasmapheresis procedure, within a seven-day period shall not exceed two thousand four hundred (2,400) milliliters.

(3) During the plasmapheresis procedure, no more than five hundred (500) milliliters of whole blood shall be removed from a Vendor at one time unless the Vendor's weight is one hundred seventy-five (175) pounds or greater, in which case no more than six hundred (600) milliliters of whole blood shall be removed from the Vendor at one time.

(D) No plasmapheresis facility within Hillsborough County may perform the plasmapheresis process on a Commercial Blod Plasma Vendor until said Vendor has been examined by a physician and issued a certificate of good health as required by the regulations of the Food and Drug Administration (FDA), of the United States Department of Health and Human Services.

(E) The Department shall keep all records in a manner which protects the rights of individuals to the confidentiality of their medical records. The disclosure of the identity of, or other information relating to Commercial Blood Plasma Vendors is expressly prohibited, except as such disclosure is directly related to and necessary for enforcement of this Ordinance or as is required by law.

(F) The Department shall assess a fee upon each plasmapheresis facility for the purpose of paying the expenses which the Department shall incur, both direct and indirect, in the implementation and maintenance of the Commercial Blood Plasma Vendor Identification System. The fee shall be based upon the number of plasmapheresis procedures performed by the plasmapheresis facility and shall be payable monthly by the facility upon receipt of an invoice from the Department. Said fee shall not exceed the amount of one dollar ($1.00) for each plasmapheresis procedure which has been performed by the facility, and the total of fees collected shall not exceed the cost to the Department of administering and maintaining the Commercial Blood Plasma Vendor identification system.

Section 7. Breath Analysis — It shall be unlawful for any plasmapheresis facility in Hillsborough County to extract whole blood or any of its products from a Commercial Blood Plasma Vendor unless, immediately prior to said extraction, the facility shall analyze the breath of the Commercial Blood Plasma Ven-

dor and determine from such analysis that the blood of the Commercial Blood Plasma Vendor does not contain alcohol in excess of 0.07 per cent, weight per volume. For the purpose of performing the required breath analysis, each plasmapheresis facility in Hillsborough County shall maintain upon the premises thereof such testing materials, equipment, supplies, and personnel as are approved by the Department.

Section 8. Reporting of Communicable Disease — Any plasmapheresis facility or employee thereof who shall discover that the Vendor evidences veneral disease, or other communicable disease shall immediately submit to the Hillsborough County Health Department a confidential report setting forth the nature of the disease and the name, address commercial blood plasma vendor identification number, and other information sufficient to identify and locate the Vendor.

Section 9. Prohibited Acts — It shall be unlawful for any person to obtain or attempt to obtain more than one plasma vendor identification card or more than one plasma vendor identification number, or for any person to attempt to utilize a vendor identification card or vendor identification number of another individual, or for any person to provide false information to a plasmapheresis facility or to the Hillsborough County Health Department in connection with the application for a Vendor identification card or identification number or in connection with any plasmapheresis procedure.

Section 10. Enforcement and Inspection — It shall be the responsibility of the Director of the Hillsborough County Health Department or his duly authorized representative to enforce the provisions of this Ordinance throughout Hillsborough County and the Director may promulgate rules and regulations necessary to carry out the provisions of this Ordinance. The Hillsborough County Health Department may make periodic inspections of each plasmapheresis facility in Hillsborough County for the purpose of determining the existence of any violation of this Ordinance.

Section 11. Denial, Suspension or Revocation of Identification Card.

A. If the Director of the Hillsborough County Health Department determines that an individual has violated a provision of this Ordinance, he may deny, suspend, or revoke any Vendor identification card or identification number, according to the following criteria:

(1) For a violation by a person who is not a registered Commercial Blood Plasma Vendor, a disqualification of that person from becoming a registered Vendor for a period not exceeding ninety (90) days for each violation.

(2) For the first violation by a registered Commercial Blood Plasma Vendor, suspension of the Vendor identification card and number and all the privileges incident thereto for a period not exceeding ninety (90) days.

(3) For the second violation by a registered Commercial Blood Plasma Vendor, suspension of the Vendor identification card and number and all the privileges incident thereto for a period not exceeding one (1) year.

(4) For the third violation by a registered Commercial Blood Plasma Vendor, suspension of the Donor identification card and number and all the privileges incident thereto for a period not exceeding five (5) years, or permanent revocation of the Vendor identification card and registration number and all the privileges incident thereto.

(B) If the Director of the Hillsborough County Health Department or his designee shall determine that a violation of this Ordinance or of any regulation promulgated hereunder has occurred, the Director may take one or more of the following actions:

(1) Service upon the person or facility in violation of a citation setting forth the violation and establishing a time within which such violation must be corrected.

(2) Initiation of a procedure for the denial, revocation, suspension, limitation, of any Commercial Blood Plasma Vendor identification card.

(3) The initiation of a judicial procedure for injunctive action against any individual or organization violating this ordinance, it being hereby declared that the performance of the plasmapheresis procedure on any Commercial Blood Plasma Vendor in violation of this Ordinance or any regulation promulgated hereunder is a nuisance inimical to the public health, welfare, and safety.

(4) Whenever the Director of the Department shall have determined the existence of a violation of this Ordinance which constitutes an immediate threat to the health, safety, or welfare of a Commercial Blood Plasma Vendor, a potential recipient of blood or plasma, or the public, and such condition cannot or will not be immediately corrected, the Director of Public Health may order the immediate closing of such plasmapheresis facility and initiate judicial proceedings seeking injunctive relief to accomplish said purpose until such time as the threat is found no longer to exist.

(C) Whenever the Director of the Hillsborough County Health Department or his duly authorized representative believes that there has been a violation of the provisions of this Ordinance, he shall serve notice of such violation in writing to the party responsible for such violation. The notice shall specify the violation and shall be deemed to be properly served and binding upon the party responsible, if a copy is served personally or served by certified mail, or if after diligent search and inquiry the party responsible for the violation cannot be found or served by personal service or certified mail, a copy of the notice is published once during each week for four (4) consecutive weeks in a newspaper of general circulation within Hillsborough County. The newspaper shall meet such requirements as prescribed by law for such purpose. Such notice shall inform the party to whom it is directed of the right to apply to the Hillsborough County Board of County Commissioners for a hearing and review of the matters specified in the notice.

Section 13. Appeal — Any person aggrieved by a decision of the Department made under the provisions of this Ordinance shall have the right to appeal such decision to the Hillsborough County Board of County Commissioners (Board). Said appeal must be in writing and received by the Board no later than ten (10) days from the date of the decision to be reviewed. The Board shall set such appeal for hearing at the earliest possible date, and cause notice thereof to be given to the appellant and the Director of the Hillsborough County Heatlh Department. The Board shall hear and consider all facts material to the appeal and render a decision promptly. The Board may affirm, reverse, or modify the action or decision appealed from providing that the Board shall not take any action which conflicts or nullifies any of the provisions of this Ordinance. The Board shall specifically state in its decision the date by which compliance must be made. The decision of the Board shall be final, and no rehearing or reconsideration shall be considered. Any party aggrieved by any decision of the Board on appeal taken to it, may apply to the Circuit Court of Hillsborough County for a review by writ of certiorari in accordance with the applicable Florida appellate rules.

Section 14. Penalty — A conviction for violation of the provisions of this Ordinance shall be punishable by a fine not to exceed five hundred dollars ($500.00) or by imprisonment in the County jail for a term not to exceed sixty (60) days or both such fine and imprisonment, as provided in Section 125.69, Florida Statutes.

Section 15. Federal Regulations — The regulations of the

Commissioner of the Food and Drug Administration of the United States Department of Health and Human Services, as they may be amended from time to time concerning plasmapheresis and source plasma (human) currently appearing at 21 CFR Part 640, Subpart G, Section 640.60 et seq, are here incorporated by reference and shall be a part of this Ordinance as though set forth herein verbatim.

Section 16. Severability — If any section, subsection, sentence, clause, provision or part of this Ordinance shall be held invalid for any reason, the remainder of this Ordinance shall not be affected thereby, but shall remain in full force and effect.

Section 17. Effective Date — This Ordinance shall take effect ninety (90) days after filing with the Secretary of State as provided by law.

STATE OF FLORIDA)
COUNTY OF HILLSBOROUGH)

I, JAMES F. TAYLOR, Clerk of the Circuit Court and Ex Officio Clerk of the Board of County Commissioners of Hillsborough County, Florida, do hereby certify that the above and foregoing is a true and correct copy of an Ordinance adopted by the Board in its regular meeting of November 26, 1980, as the same appears of record in Minute Book 76 of the Public Records of Hillsborough County, Florida.

WITNESS my hand and official seat this 5th day of December, 1980.

JAMES F. TAYLOR, JR. CLERK
BY: _____
Deputy Clerk

3/5/81

RULES AND REGULATIONS PURSUANT TO HILLSBOROUGH COUNTY ORDINANCE #80-12

Section 1. — Purpose

These Rules and Regulations are adopted to establish procedures for the monitoring of the plasmapheresis process within Hillsborough County, and the issuance of Commercial Blood Plasma Vendor Identification Cards by the Hillsborough County Health Department, under the Authority of Hillsborough County Ordinance 80-12.

Section 2. — Identification

Before being issued a Commercial Blood Plasma Vendor Identification Card pursuant to Hillsborough County Ordinance 80-12, each applicant shall furnish to the Hillsborough County Health Department:

A. One of the following items of positive identification:
1. A Social Security card exhibiting the applicant's signature;
2. A Hillsborough County voter registration card exhibiting the applicant's signature;
3. A selective service identification card exhibiting the applicant's signature;
4. A valid driver's license exhibiting the applicant's photograph and signature;
5. A United States passport exhibiting the applicant's photograph and signature;
6. Discharge documents from the United States military service exhibiting the applicant's signature.

B. A Certificate of Good Health as required by the regulations of the Food and Drug Administration (F.D.A.) of the United States Department of Health and Human Services and Hillsborough County Ordinance 80-12.

C. An Affidavit, signed by the applicant and notarized, stating that said applicant has not been detained or treated for acute or chronic alcoholism during the preceding twelve months.

Section 3 — Fees

As required by Hillsborough County Ordinance 80-12

A. The fee for issuance of the Commercial Blood Plasma Vendor Identification Card shall be two dollars ($2.00) to be paid by the applicant.

B. The fee for issuance of a duplicate Commercial Blood Plasma Vendor Identification Card, under the provisions of Section 5(B) of Hillsborough County Ordinance 80-12, shall be two dollars ($2.00), to be paid to the applicant.

C. The fee for administration and maintenance of the Commercial Blood Plasma Vendor Identification system under the provisions of Hillsborough County Ordinance 80-12, shall be the sum of one dollar ($1.00), for each plasmapheresis procedure performed, to be paid by the plasmapheresis facility.

Section 4 — Breath Analysis

Alcohol level testing as required by Section 7 of Hillsborough County Ordinance 80-12, shall be performed by a qualified operator using a model 900 Smith and Wesson breath analyzer or equipment of equal quality.

Section 5 — Inspections

Pursuant to Section 10 of Hillsborough County Ordinance 80-12, duly authorized representatives of the Director of Hillsborough County Health Department will inspect each plasmapheresis facility within Hillsborough County not less than once annually. These inspections will be made without prior notice to the plasmapheresis facility. Such inspection shall include records required to be kept by the plasmapheresis facility under Hillsborough County Ordinance 80-12.

Section 6 — Additional Tests

In the event it is deemed necessary by a physician in the interests of the public health, the Hillsborough County Health Department may require specific tests in addition to those reported and/or an independent physical examination by a physician other than the physician issuing the applicant's Certificate of Good Health.

The Hillsborough County Health Department may delay issue of the Commercial Blood Plasma Vendor Identification Card for a period of ten (10) days if deemed necessary for examination testing, or investigative purposes.

Section 7 — Phase-In Period

As of the effective date of Hillsborough County Ordinance 80-12, no plasmapheresis facility within Hillsborough County may perform the plasmapheresis process on a commercial blood plasma vendor until said vendor presents the plasmapheresis facility with a valid Commercial Blood Plasma Vendor Identification Card; provided however, during the period of ninety (90) days from the date these Rules and Regulations are adopted, each plasmapheresis facility may, nevertheless, perform the

plasmapheresis procedure on a non card holder in instance where such commercial blood plasma vendors are vendors who have previously and regularly undergone the plasmapheresis procedure at that particular facility and where such vendors appear on that facility record of current vendors as of the effective date of Hillsborough County Ordinance 80-12.

Section 8 — Falsification of Information

In the case of falsification by a commercial blood plasma vendor of any information required by Hillsborough County Ordinance 80-12, or these Rules and Regulations promulgated pursuant thereto, the Hillsborough County Health department may deny the issuance of or revoke any existing Commercial Blood Plasma Vendor Identification Card of the person falsifying any information.

CERTIFICATION

This is to certify that the foregoing Rules and Regulations were promulgated pursuant to Section 10 of Hillsborough County Ordinance 80-12.

DONALD S. KWALECK, M.D.
Director of Hillsborough
County Health Department

In The
UNITED STATES COURT OF APPEALS
For the Eleventh Circuit

Case No. 83-3014

AUTOMATED MEDICAL LABORATORIES, INC.
Plaintiff-Appellant,

vs.

HILLSBOROUGH COUNTY, FLORIDA AND
HILLSBOROUGH COUNTY HEALTH DEPARTMENT,
Defendants-Appellees.

MOTION FOR RECONSIDERATION OR
CLARIFICATION

EMELINE C. ACTON
DOLORES D. MENENDEZ
Assistant County Attorneys
Hillsborough County, Florida
Post Office Box 1110
Tampa, Florida 33601
Telephone: (813) 272-5670

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

AUTOMATED MEDICAL LABORATORIES, INC. Plaintiff-Appellant, -vs- HILLSBOROUGH COUNTY, FLORIDA AND HILLSBOROUGH COUNTY HEALTH DEPARTMENT, Defendants-Appellees.	CASE NO. 83-3014

MOTION FOR RECONSIDERATION OR
CLARIFICATION

COMES NOW Appellee HILLSBOROUGH COUNTY and requests that this Honorable Court reconsider the Motion of the American Blood Resources Association (ABRA) and Florida As-

sociation of Plasmapheresis Establishments (FAPE) For Leave To File A Brief As *Amicus Curiae* or clarify the Order entered by this Honorable Court on June 28, 1983 granting said Motion and as grounds therefor states as follows:

1. Fed. R. App. P. 29 provides that "Save as all parties otherwise consent, any *amicus curiae* shall file its brief within the time allowed the party whose position as to affirmance or reversal the *amicus* brief will support *unless the Court for cause shown shall grant leave for later filing, in which event it shall specify within what period an opposing party may answer*". (Emphasis supplied.)

2. On or about June 17, 1983, counsel for ABRA and FAPE filed with this Court a Motion For Leave To File Brief As *Amicus Curiae* and a Memorandum In Support of that Motion.

3. In that Motion For Leave To File Brief As *Amicus Curiae*, counsel for ABRA and FAPE represented that "counsel for Hillsborough County, Florida has indicated on behalf of Hillsborough County, Florida and Hillsborough County Health Department, Defendants-Appellees, that they will npt oppose this Motion provided that the *amicus* brief be filed within a time frame so as not to delay unduly the Court's consideration of this appeal and provided that the Defendants-Appellees have a reasonable opportunity to respond to the *amicus* brief".

4. Counsel for Hillsborough County did not consent on behalf of the County or the Health Department to the filing of an *amicus* brief by counsel for ABRA and FAPE although counsel for ABRA and FAPE has maintained otherwise. [See attached letters.]

5. Counsel for Hillsborough County was told by Brenda Hauck, Deputy Clerk, that the County would be receiving a request from the Court for any opposition or comments in response to the Motion.

6. Counsel for the County is aware of Fed. R. App. P. 27(a) wherein it states that a response in opposition to a motion may be filed within seven days after service of the motion; however, counsel was awaiting the letter which the Clerk's office had said was mailed before responding, but which counsel for Hillsborough County has never received.

7. This Court entered an Order dated June 28, 1983 granting the Motion For Leave To File Brief *Amicus Curiae*. Counsel for the County received a copy of said Order on July 1, 1983. That Order failed to specify the time period within which the County must file its responsive brief in accordance with Fed. R. App. P. 29.

8. Moreover, the County does, in fact, oppose the Motion which was filed some two weeks after the submission to the

Court of the final brief in this appeal and which seeks not only to inject new issues into this appeal, but also to present new evidence to the Court which was not before Judge Castagna at trial.

9. The County also opposes the Motion on the grounds that it will result in a delay in the resolution of this matter. Such a delay is particularly objectionable in that the County has voluntarily refrained from enforcing Hillsborough County Ordinances Nos. 80-11 and 80-12 and the Rules and Regulations promulgated thereunder pending a resolution of this matter despite the County's great interest in regulating this area for the protection of the public safety.

WHEREFORE, the County requests that this Court reconsider the Motion For Leave To File Brief as *Amicus Curiae* filed by counsel for ABRA and FAPE together with this Motion and deny the Motion For Leave To File *Amicus;* alternatively, if this Court refuses the County's request to reconsider the Motion For Leave To File *Amicus*, the County requests that the Court issue an Order specifying the time period within which the County must file a responsive brief.

9. The County also opposes the Motion on the grounds that it will result in a delay in the resolution of this matter. Such a delay is particularly objectionable in that the County has voluntarily refrained from enforcing Hillsborough County Ordinances Nos. 80-11 and 80-12 and the Rules and Regulations promulgated thereunder pending a resolution of this matter despite the County's great interest in regulating this area for the protection of the public safety.

WHEREFORE, the County requests that this Court reconsider the Motion For Leave To File Brief as *Amicus Curiae* filed by counsel for ABRA and FAPE together with this Motion and deny the Motion For Leave To File *Amicus;* alternatively, if this Court refuses the County's request to reconsider the Motion For Leave To File *Amicus*, the County requests that the Court issue an Order specifying the time period within which the County must file a responsive brief.

Respectfully submitted,

EMELINE C. ACTON
DOLORES D. MENENDEZ
Attorneys for Hillsborough County, Florida
Post Office Box 1110
Tampa, Florida 33601
(813) 272-5670

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a copy of the foregoing Motion for Reconsideration or Clarification has been furnished by U.S. Mail this 7th day of July, 1983 to: Richard Landfield, Attorney for American Blood Resources Association and Florida Association of Plasmapheresis Establishments, 1220 Nineteenth Street, N.W., Suite 205, Washington, D.C. 20036, and Larry A. Stumpf, Attorney for Automated, Goldstein, Goldman, Kessler & Underberg, 2606 New World Tower, 100 North Biscayne Boulevard, Miami, Florida 33132.

EMELINE C. ACTON

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 83-3014

AUTOMATED MEDICAL LABORATORIES, INC.,
Plaintiff-Appellant,

versus

HILLSBOROUGH COUNTY, FLORIDA, and
HILLSBOROUGH COUNTY HEALTH DEPARTMENT,
Defendants-Appellees.

Appeal from the United States District Court for the
Middle District of Florida

Before TJOFLAT, VANCE and HENDERSON, Circuit Judges.

BY THE COURT:

IT IS ORDERED THAT the motion of appellee Hillsborough County for reconsideration or clarification of this court's order granting the American Blood Resources Association and Florida Association of Plasmapheresis Establishments leave to file a brief as amici curiae is denied.

MOT-6H
(Rev. 5/82)

No. 83-1925

in the

Supreme Court

of the

United States

OCTOBER TERM, 1983

HILLSBOROUGH COUNTY, FLORIDA AND
HILLSBOROUGH COUNTY HEALTH DEPARTMENT,

vs.

AUTOMATED MEDICAL LABORATORIES, INC.

ON APPEAL FROM THE UNITED STATES COURT
OF APPEALS FOR THE ELEVENTH CIRCUIT

APPELLEE'S MOTION TO AFFIRM

LARRY A. STUMPF
Counsel of Record
Member, United States Supreme Court Bar
FINLEY, KUMBLE, WAGNER, HEINE,
UNDERBERG, MANLEY & CASEY
Suite 1000, Flagship Center
777 Brickell Avenue
Miami, Florida 33131
(305) 371-2600

VICTORIA L. BADEN,
On the Brief

June 26, 1984.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

TABLE OF AUTHORITIES (Continued)

Additional Authorities: **Page(s)**

No. 83-1925

---

in the

Supreme Court

of the

United States

OCTOBER TERM, 1983

HILLSBOROUGH COUNTY, FLORIDA AND HILLSBOROUGH COUNTY HEALTH DEPARTMENT,

vs.

AUTOMATED MEDICAL LABORATORIES, INC.

ON APPEAL FROM THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

APPELLEE'S MOTION TO AFFIRM

Appellee, AUTOMATED MEDICAL LABORATORIES, INC. ("AML"),[1] moves, pursuant to Sup.Ct.R. 16.1(c), to affirm the judgment of the United States Court of Appeals for the Eleventh Circuit on the grounds that the Circuit Court's resolution of the matter was so

---

[1]Pursuant to Sup.Ct.R. 28.1, the following is a list of subsidiaries (except wholly owned subsidiaries) and affiliates of AML: Dialysis Corporation of America (subsidiary of AML), Viragen, Inc. (subsidiary of AML), Florida Immunological Institute, Inc. (subsidiary of Viragen, Inc.).

eminently correct as to warrant affirmance by this Court, and that the resolution of the questions presented requires no further argument. *Equitable Life Assurance Society v. Brown*, 187 U.S. 308, 311 (1902); *Hicks v. Miranda*, 422 U.S. 332, 343-345 (1975).

STATEMENT OF FACTS AND PROCEEDINGS BELOW

This is a direct appeal, pursuant to 28 U.S.C. §1254(2), from the judgment and opinion entered on January 16, 1984 by the United States Court of Appeals for the Eleventh Circuit, holding that Hillsborough County Ordinances 80-11 and 80-12, and the rules and regulations promulgated thereunder, are preempted by federal regulation, and, therefore, violative of the United States Constitution.

On November 26, 1980, Appellant, HILLSBOROUGH COUNTY, FLORIDA ("County"), adopted Ordinances 80-11 and 80-12, purporting to regulate plasmapheresis establishments and the eligibility of donors of blood plasma.[2] Ordinance 80-11 imposed a license tax on blood plasma centers, and required licensees, among other things, to permit inspection of blood plasma centers by Appellant HILLSBOROUGH COUNTY HEALTH DEPARTMENT ("Department"). Ordinance 80-11, in addition, required blood plasma centers located within Hillsborough County to provide continuously updated

[2]Plasmapheresis is a process whereby, during a single procedure, blood is removed from a human donor, the plasma is removed from the whole blood, and the red blood cells are returned to the donor. The text of the subject ordinances and rules and regulations appears at pages A-29 through A-42 of the Jurisdictional Statement.

information to the Department regarding their ownership, employees, equipment, and facilities.

Ordinance 80-12, and the rules and the regulations promulgated thereunder, required that a blood plasma donor, prior to donating plasma, undergo a medical examination and obtain a certificate of good health, and to obtain from the Department an identification card, which identification card would have permitted the potential donor to undergo plasmapheresis for a period of six months only, and only at a single specified plasma center within Hillsborough County. Ordinance 80-12 also required a licensee plasma center to submit to the Department, on a daily basis, and as to each procedure performed, detailed information regarding the donor, reports of testing, and results of the procedures, and to pay to the Department a fee of $1.00 for each procedure performed.

AML, a Florida corporation that, through a wholly owned subsidiary corporation, operates a blood plasma center in Tampa, Hillsborough County, Florida, filed a civil action against the County and the Department in the United States District Court for the Middle District of Florida, challenging the constitutionality of the Ordinances. AML's complaint challenged the County regulatory scheme on the grounds that it was preempted by regulations of the United States Food and Drug Administration ("FDA"), (21 C.F.R. Subchapter F—"Biologics"), that it imposed an undue burden on interstate commerce, that it denied AML its right to equal protection of the law, and for other reasons.

After a non-jury trial, the United States District Court for the Middle District of Florida entered its

opinion and final judgment, on November 1, 1982, holding §7 of Ordinance 80-12 and §4 of the rules and regulations (dealing with required breathalyzer tests) unconstitutional, as impermissibly burdening interstate commerce, and upholding the remainder of the County regulatory scheme (Jurisdictional Statement, pp. A-13 through A-20).

AML appealed to the United States Court of Appeals for the Eleventh Circuit, and the County cross-appealed with respect to the portions of the Ordinances invalidated by the District Court.

The American Blood Resources Association (the national trade association for the plasmapheresis industry) and the Florida Association of Plasmapheresis Establishments participated as *amici curiae* in the appeal in support of AML's position.[3]

The *amici* filed a brief explaining the manner in which the challenged County regulatory scheme frustrated national policy expressed in the FDA regulations by, among other things, creating conflicting standards of

[3]The motion by American Blood Resources Association and the Florida Association of Plasmapheresis Establishments to file their *amici* brief in support of AML's position was not opposed in a timely manner. The suggestion in the Jurisdictional Statement (page 4) that the participation of the *amici* in the appeal was unfair or prejudicial to Appellants is without merit. The issue of preemption was in the case from the day AML's complaint was filed, and the issue was addressed by the District Court, by the panel of the Eleventh Circuit at oral argument, by the Eleventh Circuit in its opinion and by the County in its petition for rehearing. There has been no lack of fairness in the proceedings below. In any event, such an issue cannot be before this Court on this direct appeal pursuant to 28 U.S.C. §1254(2).

donor eligibility, reducing plasma availability, and causing the prices of products derived from plasma to rise, to the detriment of the many people who are dependent upon the life-saving qualities of these pharmaceutical products, all without any benefits not already provided by the federal regulations.

The Eleventh Circuit held that Ordinances 80-11 and 80-12 were invalid, because the County regulatory scheme was preempted by federal regulation of the area, under the tests enunciated in *Pennsylvania v. Nelson*, 350 U.S. 497 (1956). Accordingly, the Eleventh Circuit did not decide the other questions raised on the appeal (Jurisdictional Statement, pp. A-1 through A-12; 722 F.2d 1526 (1984)).

Hillsborough County petitioned for rehearing by panel. In its petition, the County explicated its view that the Eleventh Circuit had erred in holding that federal law preempted its Ordinances, had ignored record evidence and had misapplied the law. The Eleventh Circuit denied the petition for rehearing (Jurisdictional Statement, pp. A-22 through A-26).

ARGUMENT

I. THE STANDARDS TO BE APPLIED IN DETERMINING IF LOCAL LEGISLATION IS PREEMPTED BY FEDERAL REGULATION ARE WELL SETTLED AND FREE OF DOUBT.

As recently as June 11, 1984, this Court restated the established standards for determining a claim that local legislation is invalid as having been preempted by

federal law. *Michigan Canners & Freezers Association, Inc. v. Agricultural Marketing and Bargaining Board*, _____ U.S. _____, _____ (June 11, 1984) (slip opinion, page 7):

> Federal law may pre-empt state law in any of three ways. First, in enacting the federal law, Congress may explicitly define the extent to which it intends to pre-empt state law. E.g. *Shaw v. Delta Air Lines*, _____ U.S. _____, _____ (1983). Second, even in the absence of express pre-emptive language, Congress may indicate an intent to occupy an entire field of regulation, in which case the States must leave all regulatory activity in that area to the Federal Government. *E.g. Fidelity Federal Savings & Loan Ass'n. v. de la Cuesta*, 458 U.S. 141, 153 (1982); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Finally, if Congress has not displaced state regulation entirely, it may nonetheless pre-empt state law to the extent that the state law actually conflicts with federal law. Such a conflict arises when compliance with both state and federal law is impossible, *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-143 (1963), or when the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). *See also, Fidelity Federal Savings & Loan Ass'n, supra*, at 153.

See also, Capital Cities Cable, Inc. v. Crisp, _____ U.S. _____ (June 18, 1984) (slip opinion, page 6).

Similarly, it is well settled that, in instances where no express congressional intent to preempt is found, *Pennsylvania v. Nelson*, 350 U.S. 497 (1956), provides the tests for determining if a finding of implicit congressional intent to preempt is proper.

As detailed below, the Eleventh Circuit clearly followed, and correctly applied, the controlling standards.

II. THE ELEVENTH CIRCUIT DECISION PLAINLY SHOWS A CAREFUL AND PROPER APPLICATION OF WELL SETTLED AND CONTROLLING PRINCIPLES OF LAW.

After determining that no explicit congressional intent to preempt was applicable, the Eleventh Circuit engaged in a careful analysis of the implicit preemption issue under the criteria set forth by this Court in *Pennsylvania v. Nelson, supra*, and recently reaffirmed in *Pacific Gas & Electric Co. v. State Energy Resources Conservation & Development Comm'n*, _____ U.S. _____, 103 S.Ct. 1713 (1983). Following that analysis, the Eleventh Circuit properly determined that Ordinances 80-11 and 80-12 are preempted by the federal regulatory system.

The Eleventh Circuit's analysis is briefly summarized as follows:

1. The federal regulation of blood and blood products is so pervasive as to make it "reasonable to infer that Congress left no room for the states to supplement it" (Jurisdictional Statement, p.A-9; 722 F.2d at 1531). Section 351 of the Public Health Service

Act (42 U.S.C. §262, "the Act") requires the licensing of each establishment producing a biological product, and requires that each such product be licensed to insure safety, purity and potency; federal regulations prescribe rules regarding blood donor suitability, testing, consent and immunization, as well as proper supervision and methods of collecting, processing and labeling blood and blood components. As more fully detailed in Point IV below, the federal regulations cover virtually every phase of the plasmapheresis process.

2. The federal interest in plasmapheresis is "dominant over any local interest" (Jurisdictional Statement, p.A-10; 722 F.2d at 1532). Congress has extensively and comprehensively regulated blood collection since 1946; the Secretary of Health, Education and Welfare has established a comprehensive "National Blood Policy," and, to that end, it employs the full range of regulatory authorities vested in the Federal Government.

3. Enforcement of Ordinances 80-11 and 80-12 would adversely affect the National Blood Policy of promoting uniformity in blood banking standards and guaranteeing a continued supply of healthy donors (Jurisdictional Statement, p.A-11; 722 F.2d at 1533). While the purpose of the County's regulation of blood plasma centers is, ostensibly, an exercise of the County's police power to safeguard residents of Hillsborough County who are plasma donors, and hence similar to that of the federal regulations,[4] the Ordinances impose

[4]Ordinance 80-12 incorporates by reference the federal regulations regarding Source Plasma (Human), which is defined as the fluid portion of human blood collected by plasmapheresis and intended as source material for further manufacturing use.

additional requirements upon the centers, requirements which clearly are covered by the federal regulations but which impose additional and unnecessary burdens and expense upon the centers.

III. EXAMINATION OF THE FEDERAL REGULATION OF THE FIELD, AND OF RECENT DECISIONS OF THIS COURT, ESTABLISH THAT THE ELEVENTH CIRCUIT CORRECTLY DECIDED THIS CASE.

Plasma harvested by the plasmapheresis procedure is manufactured into life-saving pharmaceutical products known as plasma derivatives. There are three kinds of derivatives: clotting factors, protein replacement fluids, and immunoglobulins.

A product known as "factor VIII concentrate" or "AHF" (antihemophilic factors) has dramatically changed the lives of hemophiliacs by permitting both home care (self-transfusion) and prophylactic treatment. This product has significantly reduced painful and crippling joint bleeds and has extended the life expectancy of a hemophiliac from about eleven years to nearly thirty years.

The globulins protect against diseases. For example, two such products are effective against tetanus and pertussis. Another, RH immunoglobulin, has saved thousands of infants' lives and spared tens of thousands more from brain damage.

Protein replacement fluids are used as volume expanders for persons who have suffered extensive burns or for persons who are in shock as a result of

surgery or trauma. These products have saved thousands of lives on the battlefield and elsewhere.

Plasma is also used to make reagents, typing sera and chemistry products used in clinical and hospital laboratories. Modern blood banking, clinical laboratory practice, and medical diagnosis heavily depend on these products. Organ transplants are made possible by the use of various tissue typing sera.

Plasma for these products is obtained mostly from paid donors who are paid to spend the several hours necessary to collect a unit of plasma. These donors must meet the stringent FDA requirements. The facilities in which plasmapheresis is performed must also meet stringent FDA requirements, and plasmapheresis storage and manufacturing procedures must be consistent with FDA requirements. *See generally*, 21 C.F.R. Subchapter F—"Biologics".

It is generally considered safe for plasma donors to be plasmapheresed as often as twice each week if FDA's limitations are observed.[5] These regulations are extensive and detailed. They comprehensively define requirements for establishment and product licenses, good manufacturing practices, procedures for donor safety and suitability, and standards for derivatives and reagents. *See generally*, 21 C.F.R., Subchapter F—"Biologics". (These regulations also relate to the

[5]*See, e.g.*, FDA Panel on Review of Blood and Blood Derivatives, "Human Plasma as a Source for Fractionation Products," (Draft Report No. 15, 1979); Dawson, *et. al.*, "Laboratory Findings on Long Term Plasmapheresis Donors: Protein Levels," *Plasma Forum* III 209 (American Blood Resources Association 1981).

collection of whole blood and other blood products). The FDA's regulations are directed toward, among other things, assuring that all donors provide informed consent, assuring that all donors are healthy enough to donate without risk, assuring that donors do not donate in excess of a number of times deemed safe (only five times per year for whole blood, as contrasted with approximately twice per week in the case of plasmapheresis), assuring the adequacy of the collection facilities, and assuring that the plasma is free from transmissible diseases such as hepatitis, and now Acquired Immune Deficiency Syndrome.

In promulgating these regulations, the Commissioner of Food and Drugs had in mind not only meeting the requirements of Section 351 of the Act, but also the safety of individual donors:

> The promulgation of standards for licensed Source Plasma (Human) reflected the Commissioner's determination that a high priority should be attached to assuring that the source material for a variety of licensed, fractionated products . . . should be collected in a manner to ensure the safety, purity and potency of those final products.
>
> A further rationale for establishing uniform standards for this human source material was to protect the plasmapheresis donor.
>
> . . . [C]omprehensive protection requirements must be adhered to by all plasmapheresis facilities . . ."

39 *Fed. Reg.* 26161, 26162 (1974).

In addition, FDA has recognized its obligation to "insure the availability of good quality plasma," 39 *Fed. Reg.* 18615 (1974), and the relationship between an adequate supply of plasma for use in the manufacture of the resulting pharmaceutical products and healthy donors:

> . . . [T]he standards must contain provisions to protect the health of plasma donors, to insure a continued, healthy donor population to serve as a source of plasma . . . In an indirect but no less important manner the requirements for donor protection assure . . . that there will be a continuous and healthy donor population . . . [I]nadequate donor protection practices defeat one of the major purposes of the regulations: namely, to protect plasma donors.

41 *Fed. Reg.* 10762-3 (1976).

FDA's biological product regulations were not, obviously, adopted in a vacuum. In addition to the statutory framework provided by Section 351 and the new drug provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §355, the Commissioner was working within the confines of the National Blood Policy, *see*, 39 *Fed. Reg.* 32702 (1974), which declared "the policy of the United States Government" to be, among other things,

> (7) To employ the full regulatory authorities now vested in the Federal Government and to seek such additional authority as may be necessary and appropriate for the purpose of assuring uniform adherence to the highest

> obtainable standards of practice of blood banking, including plasmapheresis and plasma fractionation.

39 *Fed. Reg.* at 32703.[6]

These statutes, the National Blood Policy, the biological products regulations, and FDA's explanation of those regulations make it clear that, contrary to the County's contention, protecting the health, safety and welfare of plasma donors, and of the recipients of products derived from plasma, is the sole responsibility of the Federal Government, and that Congress intends to occupy the entire field of plasmapheresis regulation. Indeed, this Court has characterized the "overriding purpose" of the FDCA as being "to protect the public health." *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969).

Insofar as FDA's regulations evidence ample concern for safety of both donor and recipient, they demonstrate that the Federal Government, through the FDA, is engaged in protecting and promoting the "public health,

---

[6]The prior year, the Commissioner articulated a similar reason to justify a proposal requiring registration of intrastate blood banks:

> It is clear that uniform national regulation may be required with respect to manufacturing, processing and distribution of blood and blood products, not only because blood is a commodity of national significance, but also because there has been little or no State regulatory activity in this area.

38 *Fed. Reg.* 2965, 2966 (1973).

safety and welfare," as indeed it was obligated to do by acts of Congress, namely Section 351 of the Public Health Service Act and the FDCA. The interests which Hillsborough County was seeking to protect were not properly the subject of local legislation and, in any case, those interests had been carefully considered by FDA's Commissioner nearly a decade earlier when he acted to protect those very interests within the framework of the other important federal interests.

For example, cross-bleeding and its dangers (Jurisdictional Statement, p.6) were considered by the Commissioner and are the subject of federal regulation (21 C.F.R. §§640.63(c),(e); 645.65(b)(3),(4),(5),(6)). Unnecessary contamination of plasma centers by hepatitis positive plasma donors (Jurisdictional Statement, p.6) is covered by a different method than that desired by Hillsborough County, but is covered nevertheless (21 C.F.R. §640.67), and in such a way that a center that wants to produce plasma for hepatitis vaccine can do so (21 C.F.R. §610.40(d)(2),(3)), which it could not do under the County scheme. Informed consent, and assuring that donors are capable of understanding the risks involved in plasmapheresis (Jurisdictional Statement, p.6) is a specific subject of the source plasma regulations as well as a great deal of federal experience and law (21 C.F.R. §640.61). Local inspection of plasma centers (Jurisdictional Statement, p.6) merely duplicates existing federal inspection (21 C.F.R. Part 600); *see also*, 48 *Fed. Reg.* 26313 (1983), (though it presents the real risk that federal and state inspectors will impose differing requirements).

The Eleventh Circuit carefully considered the relationship between the County regulatory scheme and the federal regulations, and whether the local interests

were important enough, or sufficiently different, to justify the intrusion of the County scheme into the regulatory framework designed by the FDA. The Court properly concluded that they were neither.

Recent decisions of this Court regarding federal preemption provide additional support for the result reached by the Eleventh Circuit in the instant case. *Exxon Corp. v. Eagerton*, _____ U.S. _____, 103 S.Ct. 2296 (1983) (state pass-through prohibition of severance tax increase to first purchasers of gas preempted as to sales of gas in interstate commerce); *Pacific Gas & Electric Co. v. State Energy Resources Conservation & Development Comm'n*, _____ U.S. _____, 103 S.Ct. 1713 (1983) (federal regulation of nuclear safety preempts state legislation in that field); *Michigan Canners & Freezers Association, Inc. v. Agricultural Marketing and Bargaining Board, supra; see also, Capital Cities Cable, Inc. v. Crisp, supra.*

In its Jurisdictional Statement, the County acknowledges the comprehensiveness of federal regulation in the area of blood plasma collection (Jurisdictional Statement, p.6). The County attempts to set forth local goals, which it asserts go farther than those at the federal level: to protect residents against cross-bleeding and hepatitis contamination, to ensure that donors give informed consent, and to supplement the federal inspection process. However, as noted in detail above, and in the Eleventh Circuit's opinion, each of those goals is thoroughly addressed in, and regulated by, the federal blood collection and processing regulations. Moreover, the County scheme for attempting to meet these goals gives rise to potential conflicts between federal and

local regulation, a result which would contravene the preemption doctrine.

Moreover, Appellant's Jurisdictional Statement contains nothing that suggests specifically how the Eleventh Circuit erred, other than the assertions that preemption will not be presumed (citing *New York State Department of Social Services v. Dublino*, 413 U.S. 405 (1973)), and that legislation must be examined to determine whether federal and state regulations can coexist, and that there is a presumption against the ouster of local legislation (citing *Merrill, Lynch, Pierce, Fenner & Smith, Inc. v. Ware*, 414 U.S. 117 (1973)). These principles are correct and the cases are apt. The County overlooks, however, the critical fact that the Eleventh Circuit followed exactly the holdings of these cases.

The Eleventh Circuit made no presumptions in favor of preemption or in favor of setting aside the local legislation and it analyzed the challenged local legislation at great length to determine whether the County scheme could coexist with FDA's regulations. After a balanced, fair, and thorough analysis, the Eleventh Circuit concluded that they could not and that the local legislation must fall.

Similarly, no substantial question arises because "many other localities have recognized similar needs [for local legislation regulating plasma collection] in their communities" (Jurisdictional Statement, p.7). The County names a number of states and local governments that, according to the "Federal Department of Biologics" (sic), have plasma regulations. But the County's comfort in believing that others are also regulating plasmapheresis

is misplaced. If the legislation or regulations of those jurisdictions were before this Court, it would be apparent that most are substantially the same as the federal regulations, with few or no changes, and with no provisions which go beyond or conflict with the federal regulations. *E.g.*, Mich. Admin. Code R. 325, 2942 (1979); N.J. Admin. Code Tit. 9, §§8.5-8.8; Ohio Rev. Code Ann. §§3725.01-3725.06 (Baldwin 1982); Tenn. Admin. Comp. 1200-6-4 (1982). Although Connecticut regulates blood banks and plasma centers, *see*, Conn. Agencies Reg. 19-13-A50, we believe that there are no plasma centers operating there. The Dade County, Florida regulations are similar to those struck down by the Eleventh Circuit. In short, the existence of regulations of other jurisdictions footnoted in the Jurisdictional Statement does not demonstrate that the question presented by the County about its particular Ordinances is a substantial question.

Thus, the Eleventh Circuit decision presents no novel applications of the law of preemption, presents no arbitrary determination, and presents no unique fact situations. In sum, there is nothing suggesting that a full briefing and oral argument are merited, or that the question addressed by the Eleventh Circuit is, in its present posture, a substantial question.

CONCLUSION

The Eleventh Circuit properly determined, based upon controlling criteria set forth by this Court, that the subject Ordinances are preempted by federal regulation. The issues which Appellants attempt to raise do not justify full briefing and oral argument of this appeal. For the reasons stated herein, the judgment below should be promptly affirmed.

Respectfully submitted,

Larry A. Stumpf

LARRY A. STUMPF
Counsel of Record
Member, United States
Supreme Court Bar
FINLEY, KUMBLE, WAGNER, HEINE,
UNDERBERG, MANLEY & CASEY
Suite 1000, Flagship Center
777 Brickell Avenue
Miami, Florida 33131
(305) 371-2600

VICTORIA L. BADEN,
On the Brief

June 26, 1984.

CERTIFICATE OF SERVICE

All parties required to be served have been served by depositing on this 27th day of June, 1984 copies of this document in a U.S. Post Office, with first class postage prepaid, addressed to counsel of record at his or her post office address as follows:

Douglas R. Gardner, Esq.
Assistant County Attorney
P.O. Box 1110
Tampa, Florida 33601

Amelia M. Park, Esq.
Attorney for Hillsborough
County Health Department
Health & Rehabilitative Services
4000 W. Buffalo Avenue
Tampa, Florida 33614

Larry A. Stumpf

LARRY A. STUMPF
Counsel of Record
Member, United States
Supreme Court Bar
FINLEY, KUMBLE, WAGNER,
HEINE, UNDERBERG,
MANLEY & CASEY
Suite 1000, Flagship Center
777 Brickell Avenue
Miami, Florida 33131
(305) 371-2600

(3)

No. 83-1925

In the Supreme Court of the United States

OCTOBER TERM, 1984

HILLSBOROUGH COUNTY, FLORIDA, ET AL., APPELLANTS

v.

AUTOMATED MEDICAL LABORATORIES, INC.

ON APPEAL FROM THE
UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

REX E. LEE
Solicitor General

RICHARD K. WILLARD
Acting Assistant Attorney General

JOHN F. CORDES
MARGARET E. CLARK
Attorneys

Department of Justice
Washington, D.C. 20530
(202) 633-2217

QUESTION PRESENTED

Whether Hillsborough County Ordinances 80-11 and 80-12 and their implementing rules and regulations pertaining to the collection of blood plasma from paid donors are preempted by regulations adopted by the Food and Drug Administration governing blood and blood products, including blood plasma and plasmapheresis.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases:

Constitution, statutes and regulations:

In the Supreme Court of the United States

OCTOBER TERM, 1984

No. 83-1925

HILLSBOROUGH COUNTY, FLORIDA, ET AL., APPELLANTS

v.

AUTOMATED MEDICAL LABORATORIES, INC.

ON APPEAL FROM THE
UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE
UNITED STATES AS AMICUS CURIAE

This brief is filed in response to the Court's invitation to the Solicitor General to express the views of the United States.

STATEMENT

1. Pursuant to the provisions of the Public Health Service Act, 42 U.S.C. 262 *et seq.*, and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 321 *et seq.*, the Department of Health and Human Services (HHS) is authorized to regulate blood and blood products as biological products (42 U.S.C. 262) and

as drugs (21 U.S.C. 321(g)(1)). Under Section 351 (a) of the Public Health Service Act, 42 U.S.C. 262 (a), manufacturers and vendors of biological products, including blood products and their derivatives, must be licensed by the Secretary of Health and Human Services. Licenses are issued only upon a showing that the manufacturer's or vendor's establishment and products meet certain safety, purity, and potency standards established by the Secretary. HHS is authorized to inspect such establishments for compliance as it sees fit (42 U.S.C. 262(d) and (c)).

Pursuant to Section 351, the Food and Drug Administration's Office of Biologics Research and Review, as the designee of the Secretary,[1] regulates various types of blood products and blood banking activities, including blood plasmapheresis procedures. 21 C.F.R. Pts. 600, 601, 606, 607, 610, 640.[2] Under 21 C.F.R. Part 640, Subpart G, the FDA has established standards for plasma collected by plasmapheresis. 21 C.F.R. 640.60-640.76. These standards were adopted, and are revised from time to time, to ensure the safety, purity, and potency of the final products derived from plasma[3] and to protect plasmapheresis donors from possible abuses ranging from the collec-

[1] Pursuant to Section 361 of the Public Health Service Act, 42 U.S.C. 264, and under authority delegated to him (21 C.F.R. 5.10), the Commissioner of Food and Drugs is authorized to promulgate regulations.

[2] Plasmapheresis is defined as "the procedure in which blood is removed from the donor, the plasma is separated from the formed elements and at least the red blood cells are returned to the donor." 21 C.F.R. 606.3(e).

[3] Plasma derivatives include such products as hepatitis vaccine, albumin, and antihemophilic factor. See, *e.g.*, 21 C.F.R. 610.41, 640.50, 640.80.

tion of excessive quantities of plasma to the use of medical or collection procedures that could endanger a donor's health. See 39 Fed. Reg. 26161 (1974). The regulations require, inter alia, that a plasma center obtain the informed consent of donors before plasmapheresis is performed and that a licensed physician both examine a potential donor before he or she is accepted and be present on the premises while the procedure is being performed. 21 C.F.R. 640.61-640.63. The regulations establish minimum standards for donor eligibility, for conducting plasmapheresis, and for processing, storing, and labelling plasma units obtained during the procedure. 21 C.F.R. 640.63, 640.65, 640.68, 640.70. Recordkeeping requirements are also imposed. 21 C.F.R. 640.72. The Director of the Office of Biologics Research and Review has the power to approve variances from any of the requirements of Subpart G. 21 C.F.R. 640.75.

2. a. In November 1980, Hillsborough County, Florida adopted County Ordinances 80-11 and 80-12 (J.S. App. A29-A39), which govern the licensing and operation of commercial blood plasma donor centers. Ordinance 80-11 imposes a license fee on plasmapheresis centers, while Ordinance 80-12 "provide[s] a system for the registration and identification of and the gathering of medical data applicable to Commercial Blood Plasma Vendors as being in the common interest of the health of the people of Hillsborough County" (J.S. App. A32-A33). In addition to incorporating by reference the FDA's blood plasma regulations (*id.* at A38-A39), Ordinance 80-12 imposes certain additional donor testing and recordkeeping requirements not contained in 21 C.F.R. Subpart G. Among other things, Ordinance 80-12 requires that plasma vendors be issued county identifi-

cation cards that restrict them to donating at one particular center; it also requires that each donor be tested for hepatitis prior to registration [4] and be given a breath analysis for alcohol content before each plasma donation. Ordinance 80-12, §§ 4, 6(A), 7 (J.S. App. A33-A34, A35-A36).

b. Appellee Automated Medical Laboratories, Inc. (AML) is a Florida corporation that operates, through subsidiary corporations, eight blood plasma centers in the United States, including Tampa Plasma Corporation (TPC), in Hillsborough County. Following Hillsborough's adoption of Ordinances 80-11 and 80-12, appellee filed this action against the county and its health department in the United States District Court for the Middle District of Florida, challenging the constitutionality of the ordinances and the rules and regulations adopted to implement them. In November 1982, the court issued an opinion sustaining the ordinances and regulations (J.S. App. A13-A19). The court found no evidence of "express congressional intent to occupy the entire field of assuring high standards of practice in plasmapheresis" and concluded that the ordinances supplemented the federal regulations, rather than conflicting with them (*id.* at A17). The court also held that the ordinances did not violate the Equal Protection Clause of the Fourteenth Amendment and that most of the challenged provisions did not impermissibly burden interstate commerce (J.S. App. A18). With respect to the breathalyzer requirement, however, the court held that the county had not demonstrated that such a provision would serve the public interest to any

[4] Under federal regulations, testing for hepatitis-positive plasma is performed after plasmapheresis is completed. See 21 C.F.R. 640.67, 640.75.

greater degree than the federal regulations (*id.* at A19). Accordingly, the court held that the provisions relating to that requirement (Section 7 of Ordinance 80-12 and Section 4 of the implementing Rules and Regulations (J.S. App. A35-A36, A41)) impermissibly burdened interstate commerce and were invalid (J.S. App. A19).

c. The court of appeals reversed in part, holding that the FDA's blood plasma regulations preempted all provisions of the county ordinances (J.S. App. A1-A12). The court of appeals first noted that the federal regulatory scheme was "comprehensive" and stated that its "pervasiveness * * * makes it reasonable to infer that Congress left no room for local ordinances to supplement it" (*id.* at A8-A9). The court also concluded, based on statements by the FDA regarding the establishment of a National Blood Policy, that the field of plasmapheresis was one in which the federal interest was dominant over any state or local interest (*id.* at A10). Finally, the court concluded that the additional requirements imposed on plasma centers by the county ordinances were "burdensome and expensive" and would interfere with "the national blood policy of promoting uniformity and guaranteeing a continued supply of healthy donors" (*id.* at A11).

DISCUSSION

1. When acting within constitutional limits, Congress is empowered to preempt state law by so stating in express terms. *Jones* v. *Rath Packing Co.*, 439 U.S. 519, 525 (1977). In the absence of express preemptive language, Congress's intent to preempt state law completely in a particular area may be inferred either because " '[t]he scheme of federal regulation may be so pervasive as to make reasonable the infer-

ence that Congress left no room for the States to supplement it,' because 'the Act of Congress may touch a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject,' or because 'the object sought to be obtained by federal law and the character of obligations imposed by it may reveal the same purpose.'" *Fidelity Federal Savings & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141, 153 (1982), quoting *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Even where Congress has not completely displaced state regulation in a specific area, state law is preempted to the extent that it actually conflicts with federal law, either because it proves impossible to comply with federal and state law simultaneously (*Florida Lime & Avocado Growers, Inc.* v. *Paul*, 373 U.S. 132, 142-143 (1963)) or because state law stands as an impediment "to the accomplishment and execution of the full purposes and objectives of Congress" (*Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941)). These preemption principles apply with equal force to federal statutes and regulations. *Fidelity Federal Savings & Loan Ass'n* v. *de la Cuesta*, 458 U.S. at 153.

As this Court has repeatedly cautioned, however, preemption will not be presumed absent a clear manifestation of congressional or agency intent to supersede state legislation. *New York Department of Social Services* v. *Dublino*, 413 U.S. 405, 413 (1973). As the Court noted in *Dublino* (*id.* at 415), "[t]he subjects of modern social and regulatory legislation often by their very nature require intricate and complex responses from the Congress, but without Congress necessarily intending its enactment as the exclusive means of meeting the problem." Accord, *De*

Canas v. *Bica*, 424 U.S. 351, 359 (1976). Thus, the Court has frequently rejected preemption attacks on laws enacted pursuant to a state's police powers that paralleled federal law on the same subject or imposed more stringent requirements. *Pacific Gas & Electric Co.* v. *State Energy Resources Conservation & Development Comm'n*, 461 U.S. 190 (1983) (California statute conditioning construction of nuclear power plants on certain findings by state agency not preempted by federal law); *Florida Lime & Avocado Growers, Inc.* v. *Paul*, *supra* (California statute prohibiting importation of avocados with oil content below a certain value not preempted by Department of Agriculture marketing order allowing interstate shipment of avocados whose maturity was measured by a different standard); *Huron Portland Cement Co.* v. *City of Detroit*, 362 U.S. 440 (1960) (sustaining city's smoke abatement code against claim that federal inspection laws for maritime vessels preempted such local regulation); *California* v. *Zook*, 336 U.S. 725 (1949) (state law prohibiting same conduct by motor carriers that was prohibited by federal law not preempted); *Maurer* v. *Hamilton*, 309 U.S. 598 (1940) (Pennsylvania statute prohibiting operation on state highways of "above the cab" carrier vehicles not preempted by Interstate Commerce Commission's licensing of such vehicles to operate interstate). "'[P]reemption of state law by federal statute or regulation is not favored in the absence of persuasive reasons—either that the nature of the regulated subject matter permits no other conclusion, or that the Congress has unmistakably so ordained.'" *Alessi* v. *Raybestos-Manhattan, Inc.*, 451 U.S. 504, 522 (1981) (citations omitted).

2. With one specific exception, the FDA's blood plasma regulations do not, in our view, preempt Hillsborough County Ordinances 80-11 and 80-12. As the court of appeals acknowledged (J.S. App. A7), neither the federal blood plasma regulations nor the statutes upon which they are based expressly state an intention to preempt state law. Nonetheless, the court of appeals concluded that the county's ordinances were implicitly preempted based on three factors: the "comprehensive" nature of the federal regulations (*id.* at A8-A9), the "dominan[ce]" of federal interest in the field of blood plasma regulation (*id.* at A9-A10), and the court's perception that enforcement of state law would present a "serious danger of conflict" with the administration of the federal regulations (*id.* at A10-A11). Except with respect to one provision of the ordinances, we disagree with the court of appeals' conclusion.

a. As the court of appeals itself noted (J.S. App. A9), the fact that the FDA's blood plasmapheresis regulations are broad in scope and cover most aspects of the plasmapheresis process does not establish that the agency intended completely to displace state or local regulatory efforts in the same area. Given the complexity and technical nature of the subject, a detailed regulatory approach "was both likely and appropriate, completely apart from any questions of pre-emptive intent." *Dublino*, 413 U.S. at 415; see also *DeCanas*, 424 U.S. at 359. Accordingly, no inferences in favor of preemption can or should be drawn solely from the detailed nature of the federal plasmapheresis regulations.

b. The court of appeals erred in finding that the federal interest in the area of blood plasmapheresis is so dominant as to preclude state or local

laws that serve valid local interests and do not interfere with the FDA's regulatory scheme. Because blood products are widely distributed in interstate and foreign commerce, rather than being produced and used locally, the court of appeals may have been correct that insuring a safe, pure, and adequate supply of blood plasma is predominantly a federal rather than a state or local concern. However, state and local governments have a strong traditional interest in protecting the health of their citizens. Cf. *Head* v. *New Mexico Board of Examiners in Optometry*, 374 U.S. 424, 428 (1963) (statutes addressed to protection of public health fall "within the most traditional concept of what is compendiously known as the police power"). Protection of blood donors and vendors within their jurisdictions is a legitimate exercise of this authority. States and localities have also historically shared with the federal government an interest and an active role in assuring a safe and adequate supply of blood. For example, many federally licensed blood banks are concurrently licensed by the states in which they are located. Accordingly, we are not prepared to say that the federal government's interest in regulating blood and plasma products is so dominant that it precludes enforcement of state laws that are consistent with the federal regulatory scheme.[5]

---

[5] The National Blood Policy referred to by the court of appeals (J.S. App. A9) was established in 1974 by the Department of Health, Education, and Welfare as "a pluralistic and evolutionary approach to the solution of blood collection and distribution problems" (39 Fed. Reg. 32702) and was designed to stress cooperative efforts among the federal government and the public and private sectors (*id.* at 32703). Although FDA statements at the time this policy was an-

c. It follows that Hillsborough County's ordinances are not preempted unless it is impossible to comply with them without violating the FDA's regulations or without frustrating the objectives of the federal regulatory program. Here, "compliance with both federal and state regulations is [not] a physical impossibility." *Florida Lime & Avocado Growers, Inc.* v. *Paul*, 373 U.S. at 142-143. Indeed, Hillsborough County's ordinances expressly incorporate the FDA's plasmapheresis regulations, and nothing in the ordinances or implementing regulations requires actions that would violate the federal rules.

With one specific exception, it also does not appear at this time that the Hillsborough ordinances and regulations "stand[] as an obstacle to the accomplishment * * * of the full purposes and objectives of [the FDA]." *Hines* v. *Davidowitz*, 312 U.S. at 67. The Hillsborough provisions requiring local licensing, certification of donors, recordkeeping, reporting, and inspection are more stringent than but are not inconsistent with federal regulations. The court of appeals concluded (J.S. App. A11) that these provisions are "burdensome and expensive" and that they threaten "the national blood policy of promoting uniformity and guaranteeing a continued supply of healthy donors." Overly restrictive local legislation could threaten the national plasma supply, but

---

nounced recognized the significant role federal regulation was likely to play in its implementation, the policy, as originally announced, expressly stated that it was not intended to encompass the plasmapheresis area, which was to be addressed at a later date (*id.* at 32702). Moreover, nothing in this policy statement suggested that HEW or the FDA had any intention to regulate blood banking activities to the exclusion of state or local governments.

at this time the FDA has not identified such a threat.[6] Should a threat become apparent, the FDA would possess the authority to issue regulations preempting such local legislation. The FDA's present regulations were not intended to have this effect.

In one respect, however, the county's regulations and ordinances do conflict with federal regulations. Pursuant to Section 6(D) of Ordinance 80-12 and Section 2.B of the implementing Rules and Regulations (J.S. App. A35, A40), plasma donors are prohibited from undergoing plasmapheresis until an examining physician issues a "Certificate of Good Health as required by [FDA] regulations." Under 21 C.F.R. 640.75, the FDA authorizes specific plasmapheresis facilities to collect blood from donors who have tested positive for hepatitis B surface antigen or have other conditions that render them, by any reasonable medical description, not in "good health" as required by 21 C.F.R. 640.63(c). Collection of plasma from such individuals, under carefully controlled conditions, is necessary to produce the vaccine used to prevent hepatitis (21 C.F.R. 610.41), as well as the diagnostic products used to identify the presence of disease. Accordingly, Hillsborough's ordinances and regulations are preempted to the extent that they preclude donors who are or have been hepatitis-reactive or who are otherwise not in good health from donating plasma in a manner consistent

---

[6] Similarly, the district court found in this case (J.S. App. A15) that appellee's claims of burden and added expense in complying with the ordinances were speculative and that there was no factual basis in the record for appellee's claim that the donor population would decrease significantly if the ordinances were enforced. The court of appeals identified no basis for concluding that these findings were erroneous.

with specific exemptions granted by the FDA under 21 C.F.R. 640.75.

The primary objectives of the FDA's plasmapheresis regulations are to ensure that plasma can be collected in such a way as to assure the "safety, purity, and potency" of the final products to be manufactured from it, as well as to protect plasmapheresis donors. 39 Fed. Reg. 26161 (1974). The agency believes that its standards, if complied with, are fully adequate to achieve both of these goals. Nonetheless, with the limited exception noted above, the Hillsborough County ordinances in question here are not inconsistent with the dual federal goals of product and donor safety. Under these circumstances, and in the absence of any evidence that implementation of these local ordinances will have a significant adverse impact on the availability of plasma donors, the government believes that there is no basis for finding complete preemption in this case.

CONCLUSION

Probable jurisdiction should be noted.

Respectfully submitted.

REX E. LEE
Solicitor General

RICHARD K. WILLARD
Acting Assistant Attorney General

JOHN F. CORDES
MARGARET E. CLARK
Attorneys

DECEMBER 1984

☆ U. S. GOVERNMENT PRINTING OFFICE: 1984 461531 10112

No. 83-1925

In the Supreme Court of the United States

OCTOBER TERM 1984

HILLSBOROUGH COUNTY, FLORIDA, ET AL.,
APPELLANTS

v.

AUTOMATED MEDICAL LABORATORIES, INC.

ON APPEAL FROM THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

APPELLANT'S BRIEF ON THE MERITS

JOE HORN MOUNT
Counsel of Record
Hillsborough County Attorney
P.O. Box 1110
Tampa, Florida 33601
(813) 272-5670

EMELINE C. ACTON
Assistant Hillsborough
County Attorney

30 pp

QUESTION PRESENTED

Whether Hillsborough County Ordinances 80-11 and 80-12 and the rules and regulations promulgated thereunder regulating collection of blood plasma from paid donors are pre-empted by the federal regulatory scheme establishing standards and procedures for the collection and manufacture of plasma.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

In the Supreme Court of the United States

OCTOBER TERM 1984

HILLSBOROUGH COUNTY, FLORIDA, ET AL.,
APPELLANTS

v.

AUTOMATED MEDICAL LABORATORIES, INC.

ON APPEAL FROM THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

APPELLANT'S BRIEF ON THE MERITS

OPINIONS BELOW

The opinion (JA 40-46)[1] and final judgment (JA 47) of the United States District Court for the Middle District of Florida, William J. Castagna, J., are not reported. The opinion (JA 48-59) of the United States Court of Appeals for the Eleventh Circuit is reported at 722 F.2d 1526. The final judgment (JA 60) is not reported.

---

[1]References to the Joint Appendix are indicated by (JA), the Jurisictional Statement Appendix by (JSA) , the Record by (R) and the Transcript by (TR).

JURISDICTION

The United States Court of Appeals for the Eleventh Circuit declared on January 16, 1984, that Hillsborough County Ordinances 80-11 and 80-12 and the implementing rules and regulations are pre-empted by the federal scheme regulating plasma. After the Eleventh Circuit denied Hillsborough County's Petition for Rehearing on February 23, 1984 (JSA 22-26), the County filed its Notice of Appeal to the United States Supreme Court on April 20, 1984 (JSA 27). The jurisdiction of this Court is invoked under 28 U.S.C. §1254(2), which provides for a direct appeal to the United States Supreme Court from a decision of a federal court holding a state statute[2] to be unconstitutional. This Court noted probable jurisdiction on January 14, 1985.

CONSITUTIONAL AND STATUTORY PROVISIONS INVOLVED

1. This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding. United States Constitution, Article 6, Clause 2.

2. 21 C.F.R. §§600.3 - 680.26 (1983).

[2]The United States Supreme Court has held that, for purposes of invoking the jurisdiction of the United States Supreme Court under 28 U.S.C. §1254(2), local ordinances are treated as state statutes, *City of New Orleans v. Dukes*, 427 U.S. 297, 96 S.Ct. 2513 (1976).

3. Hillsborough County Ordinances 80-11 and 80-12 and the rules and regulations promulgated thereunder (JA 21-34).

STATEMENT OF THE CASE

Automated Medical Laboratories, Inc. [hereinafter cited as AML], which operates a plasma collection center known as Tampa Plasma Center [hereinafter cited as TPC] in Hillsborough County, Florida, filed a complaint in the U.S. Court for the Middle District of Florida against Hillsborough County, Florida [hereinafter referred to as County] and the Hillsborough County Health Department challenging the constitutionality of Hillsborough County Ordinances 80-11 and 80-12 and the implementing rules and regulations. The first count alleged that the federal government had preempted the area of plasma collection by issuing the regulations contained in 21 C.F.R. §§600.3-680.26 (1983). Following a non-jury trial, United States District Court Judge William J. Castagna rejected all of AML's constitutional attacks on the local legislation, including AML's federal preemption attack, except for the claim that §7 of Ordinance 80-12 and §4 of the rules and regulations requiring a breathanalysis test imposed an impermissable burden on interstate commerce (JA 46, 47).

AML appealed the Judgment of the District Court upholding the validity of the local legislation to the Eleventh Circuit (R 51). The County cross-appealed that portion of the Judgment which held that §7 of Ordinance 80-12 and §4 of the rules and regulations were invalid (R 55).

In its Opinion (JA 48-59) entered on January 16, 1984, the Eleventh Circuit Court of Appeals held that though no express preemption existed, the County ordinances and

regulations were implicitly pre-empted by federal regulations because of their pervasiveness, because of the dominant federal interest in the field and because of a serious danger of conflict between the local and federal regulations.

As a result of this holding, the Eleventh Circuit Court declined to reach any of the other issues raised on appeal. Further, the Court failed to address the point raised by Hillsborough County in its cross-appeal.

Accordingly, the District Court's judgment finding §7 of Ordinance 80-12 and §4 of the County rules and regulations invalid was affirmed, and the Judgment finding the remaining sections of the County ordinances and rules and regulations valid was reversed by the Eleventh Circuit Court of Appeals (JA 60).

SUMMARY OF ARGUMENT

I. Although federal regulations can pre-empt local legislation involving the public health, the administrator must clearly intend such preemption.

II. In the area of plasma regulation, the administrator has stated an intent *not* to pre-empt local law. Other comments from the FDA, as well as their representatives' testimony at trial, indicate that a cooperative approach to plasma regulation between the FDA and state and local governments is the goal of the federal government. Additionally, the local government's main concern of vendor protection is different than that of the federal government which is primarily concerned with protection of plasma.

III. Even if this goal of cooperation and intent not to pre-empt are discounted, the local legislation is not otherwise implicitly pre-empted by the federal regulations.

While the local legislation does provide the four additional vendor protections of county-wide registration, pre-testing for hepatitis, local inspection and breathalyzer testing not found in the federal regulations, none of these provisions conflict with federal law.

The Solicitor General's claim that the pre-test for hepatitis prior to the bleeding of a vendor conflicts with the federal exception allowing for the bleeding of a vendor for manufacture of the hepatitis vaccine is unfounded in that the local legislation includes the federal exception and that the pre-test for hepatitis is not the same as the test for the ingredient in the hepatitis vaccine.

IV. The Eleventh Circuit's ruling that the federal regulations implicitly pre-empt the local legislation due to the federal scheme's pervasiveness and the dominance of federal interest is unsupported by the law and the record. Mere comprehensiveness cannot imply preemption. Likewise federal uniform standards cannot imply exclusivity in the area of plasma vendor protections.

ARGUMENT

I. INTRODUCTION TO PRE-EMPTION PRINCIPLES.

A determination of whether federal law pre-empts state law begins with an examination of the federal law itself. If Congress has expressed a clear intent to pre-empt state law, the state law must yield to that intent. *Jones v. Rath Packing Co.*, 430 U.S. 519, 97 S.Ct. 1305 (1977).[1]

[1] *See, also, Smith v. Pingree*, 651 F. 2d 1021 (5th Cir. 1981) (Unit B). The pre-emptory language from laws under review in the *Jones* and *Smith* cases are, respectively, as follows: "Marking, labeling, packaging, or ingredient requirements in addition to, or different than those made under this Act may not be imposed by any state," *Jones*

Absent an express statement, an implicit intent to pre-empt may be attributed to Congress where: it has left no room for supplementary laws, compliance with both federal and state law is impossible, or the state law stands as an obstacle to congressional purpose and objectives. *Capital Cities Cable, Inc. v. Crisp*, 104 S.Ct. 2694, 2700 (1984).

A presumption against implicit federal preemption exists where the state legislation deals with the health and welfare of its citizenry.[2]

Although federal regulations may pre-empt state law just as federal statutes can, the pre-emption analysis shifts its focus. Where Congress has given an administrator the authority to promulgate regulations, whether those regulations pre-empt state law depends, not upon express congressional authorization, but upon whether the administrator intended to pre-empt state law. If such an intention

---

1 Con't.
at 529, 97 S.Ct. 1312 (1977); "[N]o state . . . may establish . . . with respect to a device intended for human use any requirement . . . which is different from, or in addition to, any requirement applicable under this statute," *Smith*, 651 F. 2d at 1022 (5th Cir. 1981) (Unit B). In spite of this language in *Smith*, the Fifth Circuit held that Florida law was *not* pre-empted.

[2]*See, e.g., Head v. New Mexico Board of Examiners in Optometry*, 374 U.S. 424, 428, 83 S.Ct. 1759, 1762 (1963), " . . . the statute here involved is a measure directly addressed to protection of the public health, and the statute thus falls within the most traditional concept of what is compendiously known as the police power. [footnote omitted] The legitimacy of state legislation in this precise area has been expressly established. [Citation omitted]."; and *Jones v. Rath Packing Co., supra* at 525, 97 S.Ct. 1305, 1309, quoting from *Rice v. Santa Fe Elevator Corp.* 331 U.S. 218, 230, 67 S.Ct. 1146, 1152 (1947), "we start with the assumption that the historic police powers of the State were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."

exists, then a second question of whether the administrator's action has exceeded the scope of his delegated authority must be answered. *Fidelity Federal Savings & Loan Ass'n. v. De la Cuesta*, 458 U.S. 141, 153-154, 102 S.Ct. 3014, 3022-23 (1982); *United States v. Shimer*, 367 U.S. 374, 381-383, 81 S.Ct. 1554, *1560* (1961).

II. FEDERAL LAW AND ADMINISTRATIVE HISTORY REVEAL AN INTENT NOT TO PRE-EMPT LOCAL PLASMA LAWS.

An examination of the congressional and administrative plasma laws reveal neither congressional intent nor authorization to pre-empt the area.[3] In fact, the administrator specifically announced that *no* preemption of state or local plasma laws was intended. The Commissioner of the Food and Drug Administration[4] [hereinafter cited as FDA] stated in response to inquiries about the initial plasma regulations:

> Some comments expressed concern that the licensing of Source Plasma (Human) would preempt State and local laws governing plasmapheresis. *These regulations are not intended to usurp the powers of State or local authorities to regulate plasmapheresis procedures in their localities.* Rather, the intention is to assure the safety, purity and potency of their biological product when it is shipped in interstate commerce pursuant to Section 351 of the Public Health Service Act. 38 Fed. Reg. 19365

---

[3]*See*, 21 U.S.C. §§321 *et seq.*; 42 U.S.C. §§262 *et seq.*; 21 C.F.R. §600. 3-680.26; (JA 54-55).

[4]The Commissioner of the FDA has authority from the Secretary of the Department of Health and Human Services to promulgate regulations under 21 C.F.R. §5.10. Congress gave the Secretary the authority to regulate blood and blood products in 42 U.S.C. §§262 *et seq.* and 21 U.S.C. §§321 *et seq.*

(1973) [Emphasis supplied].[5] Therefore, the initial and primary test under *De la Cuesta* for determining whether federal regulations pre-empt local laws, that is, whether the administrator meant to do so, has not been satisfied.

Moreover, even if this statement of express intent *not* to pre-empt is discounted, no implicit pre-emption by the FDA can be found either.

The "National Blood Policy", which the Eleventh Circuit Court of Appeals cited as evidence of the need for uniformity and federal dominance in the field of plasmapheresis, specifically excludes any application of the policy to commercial plasmapheresis.[6] Moreover, that National Blood Policy was intended to involve" . . . *all relevant public* and private *sectors and Federal Government agencies* in a *cooperative* effort to provide the best attainable blood services." *Id.* at 32703 [Emphasis supplied]. In commenting upon an alternative plan suggested by HEW Task Force on Blood Banking[7] for the implementation of the policy, the Acting Assistant Secretary criticized the plan for not acknowledging:

> the actual and potential role of duly constituted authority, such as *State Departments of Health*, in the process of designating regional programs. This is a significant omission, in light of the rather major role played by the Departments of Health in several states, and, *particularly the future role that some Departments of Health will certainly play* in the course of regionalizing their respective State's blood banking facilities. *Id.* [Emphasis supplied]. The Department intended that the policy take "due regard for the role of *the county medical society*, among others in the process of a regionalization of blood banking activities." *Id.* [Emphasis supplied].

In line with this "cooperative" effort taking due regard for local input, the Federal Register contains one reference to state regulation in the area of blood and blood components, implicitly recognizing a dual system of federal and local regulation.[8] Further, FDA representatives testified at trial that the enforcement of the County legislation would not conflict with their duties under the federal regulations and would, in fact, be helpful.[9]

---

[5]The County did not have the opporunity to direct the Eleventh Circuit to this citation prior to its decision. The court denied the County the opportunity to respond to the issue of preemption which was raised initially by an *amicus* brief filed two weeks after the submission of the final briefs by the parties. (JSA 43-47, 22-26)

[6]The Acting Assistant Secretary of Health stated as follows: "Although this comprehensive policy accelerates the evolution of an all-voluntary supply of blood and blood components, *it leaves untouched*, for the time being, the commercial acquisition of plasma and the preparation and marketing of plasma derivatives, and the commercial acquisition of blood for preparation of diagnostic reagents." 39 Fed. Reg. 32702 (1974) [Emphasis supplied].

[7]Two members of that Task Force, Dr. Paul Schmidt and Dr. Frank Coleman testified as experts in the field of plasmapheresis in favor of the County's plasma laws at trial. (TR 177-208)

[8]"Approximately ten states have inspection or licensing provisions with respect to the collection and processing of blood and blood components. The Commissioner finds these programs are inadequate to keep blood containing hepatitis virus from the channels of interstate commerce." 39 Fed. Reg. 18614-5 (1974).

[9]Herbert W. Smith, an FDA Inspector based in Tampa, testified that local County inspections would not interfere with or hinder his job. (TR 215-216) Edward R. Atkins, Director of Compliance for the FDA District Office in Orlando, testified that the enforcement by the county of their regulations would not cause any difficulties for his office and that "any additional inspection of these [plasma] firms would be helpful." (TR 224-225)

Finally, an examination of the congressional and administrative history reveals a different emphasis in the federal legislation than that in the local regulations. The purpose of the local regulations is to protect the health of the people of Hillsborough County.[10] The federal legislation, rather than basing its jurisdiction in local health issues, "rests upon the constitutional power resident in Congress to regulate interstate commerce. [citation omitted]." *United States v. Walsh*, 331 U.S. 432, 434, 67 S.Ct. 1283, 1284 (1941).[11]

In August of 1972, the FDA took over blood regulatory activities from the National Institutes of Health, 37 Fed. Reg. 12865 (1972), and promulgated comprehensive plasma regulations. 37 Fed. Reg. 17419 (1972).[12]

As an adjunct to those plasma regulations and to "insure there is a continued healthy donor population to serve as a source of plasma," 37 Fed. Reg. 17420 (1972), the FDA included regulations designed to protect plasma vendors. Although the federal government has, thereafter, announced that its regulations are designed both to protect the product and the source, its jurisdiction to regulate vendor protection has always been based upon its primary concern for the product as it passes from state to state.[13]

---

[10](JA 24,25)

[11]The Court was speaking specifically of the Federal Food, Drug and Cosmetic Act, [21 U.S.C. §§301 *et seq.*].

[12]The federal government began regulating the sale of blood and blood products as early as 1902 under the "Virus-Toxin Law" which was recodified in 1944 in the Public Service Health Act, 42 U.S.C. 262, 263 and which was specifically amended to add the words "blood and blood components or derivatives" in 1970 at 42 U.S.C. 351, 352. Division of Biologics Standards, National Institutes of Health, U.S. Dept. of Health, Education and Welfare, *Legislative History of the Regulation of Biological Products*, (June 1971).

[13]*See United States v. Walsh, supra*. Other comments by officials in the Federal Register which illustrate that the primary federal con-

III. LOCAL PLASMA LAWS DO NOT CONFLICT WITH FEDERAL LAWS BUT SUPPLEMENT AND REINFORCE THEM:

While the initial concern of the federal government is the product, that of Hillsborough County is the *source* of that product—its people. County officials found that the gathering of medical data on, and the identification of, plasma vendors promotes the public health. (JA 24-25)

The testimony at trial established four provisions for the protection of plasma vendors which are not found in

---

13 Con't.

cern is to ensure a safe and plentiful product in interstate commerce include the following:

> Human blood is a significant source of hepatitis and other communicable diseases, and if not collected, processed and distributed under appropriate standards, *may contaminate the product*. Approximately ten states have inspection or licensing provisions with respect to the collection and processing of blood and blood components. The Commissioner finds these programs are inadequate *to keep blood containing hepatitis virus from the channels of interstate commerce*. 37 Fed. Reg. 18614-18615 (1974) [Emphasis supplied]; and,
>
> Certain aspects of the donor protection requirements *directly affect the safety, purity and potency of the plasma*, such as those provisions concerning donor suitability that are designed to assure that plasma is free of disease-carrying agents. In an indirect but no less important manner, the requirements of donor protection *assure* as the Commissioner stated more than 3 years ago that there will be a *continuous and healthy donor population*. Finally, the Commissioner believes that it is an *inherent obligation of government to assure that where standards are established for products, the public health factors that are integral to the product must be considered and protected*. Such action is necessary and proper in the exercise of the underlying authority. 41 Fed. Reg. 10762 (1976) [Emphasis supplied].

the federal plasma regulations and which serve to protect local interests. These additional protections as as follows: 1) the establishment of a county-wide plasma vendor registration system; 2) the requirement that prospective plasma vendors submit to a test for hepatitis prior to their plasma being drawn; 3) the provision for enforcement of the local legislation in Hillsborough County by the County Health Department; 4) the requirement that prospective vendors undergo a breath analysis so as to determine the alcohol content of their blood.[14]

III.(a) VENDOR REGISTRATION

The purpose of a county-wide plasma vendor registration system is to prevent the excessive bleeding of vendors beyond the levels and frequency set by the federal regulations. The vendors are able to overbleed themselves, and thus jeopardize their health, through the practice of cross-bleeding whereby they go from plasma center to plasma center selling their plasma at each center they visit. Although the federal regulations set limits for the frequency and levels beyond which vendors cannot be bled and require each individual center to maintain records on each vendor to protect against over-bleeding at any one center, those regulations do not require that these centers exchange bleeding lists with one another and do not otherwise protect against excessive cross-bleeding which takes place at different centers (TR 63, 165-166, 183, 215, 224). The centers, likewise, do not exchange such information on a

[14]The breathalyzer requirement was the only portion of the local legislation which the trial court held invalid. Judge Castagna ruled that although this portion of the local legislation was not preempted, it imposed an impermissible burden on interstate commerce (JA 46-47). The County's cross-appeal on this issue was not ruled upon by the Eleventh Circuit.

regular basis. Mili Lamas, Automated's Vice President, stated that the employees at TPC "don't have a way of knowing whether he [the vendor] has donated at another center before or not." (TR 63). While Ms. Lamas testified that the employees at TPC "voluntarily" check with another center in Hillsborough County if they have a problem identifying a prospective vendor, AML stipulated that TPC doesn't exchange donor lists with any other center in Hillsborough County. (R 38, p. 7, para. 27) Further, even if TPC were to compare its records at another center in Hillsborough County on a regular basis, neither TPC nor any other plasma center would be under a duty to engage in or continue such an exchange of information. Thus, Hillsborough County's only assurance of protection against excessive over-bleeding or cross-bleeding lies in the local legislation.[15]

III.(b) PRE-TESTING FOR HEPATITIS
i) REQUIREMENTS IN ADDITION TO FEDERAL REGULATIONS

The local legislation also requires that prospective vendors have a negative hepatitis test result before they can receive a vendor identification card from the County Health

[15]The Eleventh Circuit's lack of understanding of the difference between the federal single-center over-bleeding enforcement provisions and the County's multi-center cross-bleeding provision is obvious from the statement in its opinion that "TPC can deter any attempted donation" which would result in a health risk to the vendor or in a violation of the federal bleeding limits through the use of its "permanent donor record file" which contains bleed information only at TPC. (JA 51-52). Of course, such a file would be quite effective at eliminating excessive cross-bleeding if the vendor was only allowed to be bled by one center which followed TPC's practices. This is the goal of the center-specific identification card provision in the County's regulations.

Department (TR 150). This requirement is in contrast with the federal regulations which require plasma center employees to draw a blood sample from a vendor after they have already bled that vendor. The sample is then sent off to a lab for testing while the drawn plasma is kept at the center, 21 C.F.R. §610.40. (TR 66).

The local legislation would prohibit, absent written authorization as provided for in 21 C.F.R. §640.75, any prospective plasma vendor with a history of viral hepatitis or contact with hepatitis from obtaining a County Vendor Identification Card, selling his or her plasma and thereby exposing other vendors, center personnel as well as any other people present in the center, to the danger of hepatitis contagion.[16] Automated emphasizes the use of sterile plastic bags and tubing as though this would eliminate the risk of hepatitis. Even Ms. Lamas, however, admitted at trial that a plasma bag may break or that plasma may spill during the plasmapheresis procedure (TR 65-66). Additionally, Dr. Kwalick testified that more persons potentially can be contaminated by hepatitis-positive plasma under the federal regulations than under the local legislation (TR 150-151). This protection is particularly necessary for *paid* plasma vendors such as those in Hillsborough County, because paid blood vendors have a much higher incidence of hepatitis infection than volunteer blood donors. (JA 45, TR 155-156).[17]

---

[16]The Associate Commissioner for Compliance with HEW, Sam D. Fine, acknowledged the government's concern with "thousands of technicians" who handle plasma infected with hepatitis B antigen while unaware of that infection. 39 Fed. Reg. 26162 (1974). Although this comment was listed as a rationale for the labeling requirements of the federal regulations, it supports the County regulations requiring the testing of the plasma vendor as well.

[17]*See, also,* J. Walsh, P. Schmidt *et al., Post Transfusion Hepatitis After Open-Heart Operations,* 211 JOURNAL OF THE AMERICAN MEDICAL

III.(b)(ii) THE SOLICITOR GENERAL'S ASSERTION THAT THIS PROVISION CONFLICTS WITH FEDERAL LAW IS UNFOUNDED

The Solicitor General as Amicus Curiae to the Court has stated that the County's requirement that a vendor be in "good health" conflicts with the federal regulations which allow for the bleeding of individuals with hepatitis B surface antigen, the source for hepatitis vaccine. 21 C.F.R. §640.75. However, this conflict is illusory for several reasons.

First, the County's requirement for the good health of a vendor are the same as those requirements in the federal regulations (JA 27, Section D) and thus does not conflict with them or require less or more than they do. Secondly, the County incorporates by reference 21 C.F.R. §640.75 which the Solicitor General cites as the federal regulation allowing for the bleeding of individuals who are not in good health for the express purpose of obtaining plasma for production of hepatitis vaccine and diagnostic products. Thus, the provision allowing a plasma center, upon written approval of the Director of the Bureau of Biologics, to collect plasma from those not eligible for a good health certificate would be upheld and enforced by the County. Thirdly, those who have a history of viral hepatitis or who may be infected with hepatitis, which are those not eligible to receive a vendor card from the County, are not the same as those vendors who carry the hepatitis B surface antigen which is necessary to produce the hepatitis vaccine. In a

---

17 Con't.
ASSOC. 261-265 (Jan. 12, 1970) (wherein the authors state that "the chance of hepatitis developing is higher among patients given blood obtained from our commercial blood sources than among patients given blood supplied by local volunteer donors.") *Id.* at 264.

journal published by the federal government, the Committee on Viral Hepatitis found that "[a] chronic carrier of the antigen may or may not have demonstrable evidence of related liver disease." The Committee On Viral Hepatitis, U.S. Department of Health, Education and Welfare, *The Public Health Implications Of Hepatitis B Antigen In Human Blood*, 23 MORBIDITY AND MORTALITY 125 (1974).[18]

Finally, the supposed conflict asserted by the Solicitor General was never presented to the trier of fact for a determination of whether such a conflict does exist. As this Court has stated, it will not assume in advance that "a State will so construe its law as to bring it into conflict with the federal constitution or an act of Congress." *Allen-Bradley Local v. Wisconsin Employment Relations Board*, 315 U.S. 740, 746, 62 S.Ct. 820, 824 (1942). In fact, a representative of AML testified at trial that a vendor whose plasma has tested positively for hepatitis is told if he returns to the center that "he no longer can donate plasma nor whole blood at our facility or anywhere else, and he is permanently rejected as a donor." (TR 36-37). In addition, as noted by the Eleventh Circuit, TPC destroys any unit of plasma where a sample of it is found to be contaminated with hepatitis (JA 51). Hepatitis contaminated plasma obtained in Hillsborough County under the federal regulations is not used. Accordingly, no conflict between the two regulations is apparent and, in light of the reasons listed above, cannot be

[18]*See, also,* P. Holland, *et al., Viral Hepatitis Markers in Soviet and American Blood Donors*, 20 TRANSFUSION 504 (Jan.-Feb. 1980) (wherein 1.5% of vendors in Tampa with no history of viral hepatitis were carriers of the antigen), LIVER AND BILIARY DISEASE 661 (R. Wright *et al.* ed. 1979) ("It can be argued that a carrier of HB_5Ag [the antigen] should be described as one who is asymptomatic and who has no histological evidence of liver disease. In such individuals, histological evidence of hepatitis may not be present, ...").

presumed to exist by this Court prior to the County actually enforcing its regulations.[19]

III.(c) LOCAL INSPECTION AND ENFORCEMENT

The local legislation also provides for the enforcement of its provisions as well as the provisions of the incorporated federal regulations by the Hillsborough County Health Department. The two FDA inspectors based in Tampa and charged with the enforcement of the federal plasma regulations must cover an area including nine (9) counties and must enforce all of the FDA regulations in that area (TR 210). Although these inspectors are assisted at times by other FDA personnel, no one is regularly at the local office to answer any incoming calls (TR 210-211).

Additionally, Dr. Schmidt testified that the Bureau of biologics, the division responsible for enforcement of federal plasma regulations, was to be merged with the Bureau of Drugs, leaving a smaller group with more responsibilities (TR 188). He also stated that even prior to the merger, federal inspectors have been to his blood bank only once in the last thirty-nine (39) months though they were required to inspect once a year (TR 187).[20]

III.(d) BREATHALYZER TEST

Finally, the local legislation requires that a prospective vendor undergo a breath analysis prior to his or her plasma being drawn so that the blood alcohol level can be deter-

[19]Respondent filed its lawsuit against the County approximately one month after the local legislation was passed by the Board of County Commissioners and the County has not enforced it pending an ultimate judicial decision on the claims raised in that lawsuit.

[20]As the Eleventh Circuit noted, (JA 58), inspections by the FDA were cut from one every year to one every *two* years as of July 7, 1983. 48 Fed. Reg. 26313 (1983).

mined (JA 28, 33, TR 184-185,215). The results of the test must not show more than 0.07 percent alcoholic content in the vendor's blood (JA 28, 33). Each plasma center is required to maintain upon its premises the equipment and personnel required for the purpose of performing the breath analysis (JA 28, 33).

These provisions would ensure that the vendor be capable of giving truly informed consent prior to submitting to the risks of the plasmapheresis procedure (TR 149-150). Additionally, these provisions are intended to ensure that each vendor will have the capacity to assist in the return of the necessary blood cells following the withdrawal of his or her plasma (TR 149-150)[21] and that each vendor will give an accurate medical history (TR 149-150, 207-208). As Dr. Coleman testified, an intoxicated vendor is totally unreliable in relating his or her medical history to center personnel (TR 207-208).

These protections provided by this breathalyzer requirement are not otherwise provided for by the federal regulations. The federal regulations require only that center personnel "interview" a prospective vendor. On the basis of this interview alone, the "interviewer" is expected to be able to ascertain the sobriety or intoxication level of a prospective vendor. 21 C.F.R. §640.63(d) (TR 183-184). The federal regulations do not contain any requirements as to the qualifications of that interviewer. 21 C.F.R. §640.63.

[21] As noted by the FDA, returning to a vendor the red blood cells of another vendor "can lead to a hemolytic transfusion reaction and death." 30 Fed. Reg. 26161 (1974). The Court need only consult local newspaper to find that these reactions occur even with the federal regulations in place. *See, e.g.*, Kalfus, *Plasma Center Puts Wrong Blood Back in Man*, TAMPA TRIBUNE, Feb. 8, 1985, at 1-B; ST. PETERSBURG TIMES, Feb. 10, 1985, at 17-B; MIAMI HERALD-TRIBUNE, Feb. 9, 1985, at 2-B.

Thus this interviewer need not be a physician nor even an employee possessing any medical training.

Dr. Schmidt, an expert in the plasmapheresis field, testified that the federal regulations do not provide "a valid way to exclude some people who might be under the influence of alcohol." (TR 184). Dr. Coleman, also a plasmapheresis expert, testified that the "subjective observation of somebody in the center" is not an adequate way to measure vendor intoxication (TR 205). Thus, the County presented unrefuted evidence at trial in support of its position that the objective breathalyzer requirement of the local legislation affords valuable protection to the prospective vendor which is not available in the subjective evaluation mandated by the federal regulations but which fulfills the same purpose as and does not conflict with those regulations.

IV. THE ELEVENTH CIRCUIT'S RULING THAT FEDERAL REGULATIONS IMPLICITLY PRE-EMPT THE LOCAL LEGISLATION IS INCORRECT.

The local legislation is neither explicitly nor implicitly pre-empted by the federal plasma regulations which it supplements and reinforces. The Eleventh Circuit's ruling that the local legislation is implicitly pre-empted because it conflicts with the federal scheme which is pervasive and dominant is contradicted by the two regulatory schemes themselves, the administrative history and the record. As noted earlier, the Commissioner of the FDA stated an express intent *not* to pre-empt and FDA representatives testified that no practical conflicts would arise in enforcing the two regulatory schemes. In light of this, the mere comprehensiveness of the federal scheme cannot serve to displace the local law. Moreover, the federal regulations *do* leave

room for supplementation in the area of vendor protection, as Dr. Schmidt and Dr. Coleman testified. The county has moved in to fill that void. Comprehensiveness cannot imply pre-emption particularly where as here, the federal government had to promulgate regulations sufficient to govern in states without any regulatory activity.[22] Conversly, if Congress or the FDA had intended to pre-empt this area, a clear intent to do so is necessary inasmuch as some states did have regulations in existence when the Commissioner declared the federal regulations.[23]

The Eleventh Circuit's opinion that the federal interest in plasma is dominant over any local interest because the federal regulations establish a uniform national blood policy is invalid for two reasons. First of all, that national policy does not encompass the commercial collection and manufacture of plasma, as noted earlier.[24] Secondly, the federal uniform standards constitute only a minimum level of public health protection to ensure an uncontaminated product beyond which local governments may impose additional reasonable standards to protect that product's

[22]*See, e.g., New York State Dept. of Social Services v. Dublino,* 413 U.S. 405, 415, 93 S.Ct. 2507, 2515 (1973), "This would be especially the case when the federal work incentive provisions had to be sufficiently comprehensive to authorize and govern programs in states which had no welfare work requirements of their own as well as cooperatively in states with such requirements." As cited earlier, the Commissioner of the FDA acknowledged that only ten states had plasma inspection or licensing provisions when he promulgated the federal regulations. *See, pp.9, 10, nn. 8 & 13, supra.*

[23]*See, id.* at 414, 93 S.Ct. 2513, "Moreover, at the time of the passage of WIN in 1967, 21 states already had initiated welfare work requirements as a condition of AFDC eligibility. [footnote omitted] If Congress had intended to pre-empt state plans and efforts . . . , such intentions would in all likelihood have been expressed in direct and unambiguous language."

[24]*See,* p.8, n.6, *supra.*

source.[25] As a member of the federal government's own advisory commission testified, additional standards had been suggested to the federal officials, who had declined to include them in their regulations.[26]

The ruling by the Eleventh Circuit that the local legislation is implicitly pre-empted by the federal regulations is not supported by the law or the record and misapprehends the intent of a cooperative system based upon minimum federal standards supplemented and enforced by local governments when the need arises, as it has in Hillsborough County , Florida. The local legislation should be upheld by this court.

[25]*Cf. Florida Lime and Avocado Growers, Inc. v. Paul,* 373 U.S. 132, 83 S. Ct. 1210 (1963) where federal regulation over the picking of avocados at the source did not prohibit California from passing laws governing its acceptance of the product in the marketplace.

[26]Dr. Paul J. Schmidt testified that the Commission "made certain recommendations as to what could be done, and not all of those recommendations are in the federal regulations. The federal government chose not to accept all of those opinions." (TR 183-185) He also stated that the "specific point of the identification and the regional registries was addressed and recommended. The federal regulatory people chose to ignore that when they wrote their regulations." *Id.*

CONCLUSION

The County requests that this Court reverse the holding of the Eleventh Circuit and enter a ruling that Hillsborough County Ordinances No. 80-11, No. 80-12 and the Rules and Regulations promulgated thereunder are not pre-empted by congressional law found at U.S.C. §§ 321 *et seq.* and 42 U.S.C. §§ 262 *et seq.* nor by the administrative regulations found at 21 C.F.R. §§ 600.3-680.26 and, further, that there is no present conflict between the local and federal scheme. In the alternative, the County requests that this Court find that no pre-emption exists and remand the case back for a determination of whether any conflict between the federal and local regulations exists.

Respectfully Submitted,

JOE HORN MOUNT
Hillsborough County Attorney
P.O. Box 1110
Tampa, Florida 33601
(813) 272-5670

EMELINE C. ACTON
Assistant Hillsborough County Attorney
P.O. Box 1110
Tampa, Florida 33601
(813) 272-5670

CERTIFICATE OF SERVICE

All parties required to be served have been re-served by depositing on this 2nd day of March, 1985, three printed copies of this document with an overnight delivery service, addressed to counsel of record at his or her post office address as follows:

Larry A. Stumpf, Esq.
Finley, Kumble, Wagner,
Heine, Underberg, Manley
& Casey
Counsel for Appellee
Automated Medical
Laboratories, Inc.
Suite 1000 Flagship Center
777 Brickell Avenue
Miami, Florida 33131

Paul Larkin, Esq.
Counsel for Amicus
United States Government
Dept. of Justice
Solicitor General's Office
10th and Constitution Ave.
Room 5634
Washington, D.C. 20004

Joyce Holmes Benjamin, Esq.
Counsel for Amicus
The Academy for State and
Local Government
The State & Local Legal Center,
Suite 349
444 North Capital Street, N.W.
Washington, D.C. 20001

Richard Landfield, Esq.
Landfield, Becker & Green
Counsel for Amicus
American Blood Resources
Assoc.
1220 Nineteenth Street, N.W.
Suite 205
Washington, D.C. 20036

JOE HORN MOUNT
Counsel of Record
Hillsborough County Attorney
Member, United States
Supreme Court Bar
Post Office Box 1110
Tampa, Florida 33601
(813) 272-5670

(1)

No. 83-1925

IN THE

Supreme Court of the United States

OCTOBER TERM 1984

HILLSBOROUGH COUNTY, FLORIDA AND
HILLSBOROUGH COUNTY HEALTH DEPARTMENT

V.

AUTOMATED MEDICAL LABORATORIES, INC.

**ON APPEAL FROM
THE UNITED STATES DISTRICT COURT
FOR THE ELEVENTH CIRCUIT**

JOINT APPENDIX

JOE HORN MOUNT
EMELINE C. ACTON
Hillsborough County
Attorneys
P.O. Box 1110
Tampa, Florida 33601
(813) 272-5670
Counsel for Appellant

LARRY A. STUMPF
Finley, Kumble, Wagner,
Heine, Underberg,
Manley & Casey
Suite 1000, Flagship Center
777 Brickell Avenue
Miami, Florida 33131
(305) 371-2600
Counsel for Appellee

JURISDICTIONAL STATEMENT FILED MAY 22, 1984
PROBABLE JURISDICTION NOTED JANUARY 14, 1985

63 pp

INDEX

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

CLOSED NOV. 1, 1982

Plaintiffs
AUTOMATED MEDICAL LABORATORIES INC

Defendants
HILLSBOROUGH COUNTY, FLORIDA and
HILLSBOROUGH COUNTY HEALTH DEPARTMENT

Cause
(Cite the U.S. Civil Statute under which the case is filed and write a brief statement of cause)
28 USC S1343 (3) and 42 USC S1983, to enjoin the enforcement of two Hillsborough Co ordinances & the regulations issued thereunder on grounds that they are unconstitutional under the commerce & supremacy clauses of the fifth and fourteenth amendments

Attorneys

Larry A. Stumpf Esq
Goldstein Goldman Kessler & Underberg
Suite 2606
New World Tower
100 N. Biscayne Blvd.
Miami, Fl 33132

Janice Sortor
Amelia M. Park
Dist VI Legal Counsel
Dept of Health & Rehabilitative Serv
4000 West Buffalo Ave
Tampa, Fl 33614
813 272-2540

Joe Horn Mount & Emeline C. Acton Esq
Attys. for deft. Hillsborough Co.
Post Office Box 1110
Hillsborough Co. Courthouse
Tampa, Florida 33601

Date		NR	Proceedings
1981			
Dec	21	1	Complaint Filed (summ issued)
Jan	12	2	S&C ret ex 1-7-82 re: President Chairman or chief Exec. of Hillsborough Cty,
	12	3	S&C ret ex 1-7-82 re: Dr. Donald Kwalick Director Hillsborough co Health Dept
	27	4	Deft M/to dismiss;memo of law in supp
Feb	12	5	S&C ret ex 1-29-82 re: E J Salcines State Atty in Hillsborough Co
Jan	29*	6	Deft notice of appearance of counsel
Feb	4	7	Pltfs memo of law in supp of pltfs M/for a preliminary injunction

	4	8	Pltfs M/for preliminary injunction
	10	9	Notice of hearing on M/for preliminary injunction Feb 17, 1982 at 2:00 pm rm 435 before WC (m)
	12	10	ORDERED: hearing previously set for Feb 17, 1982 is cont, pltf shall file a response to defts M/to dismiss by Mar 1, 1982, defts shall file a response to pltfs M/for preliminary injunction by Mar 7, 1982, trial of this action on the merits will be consolidated with the hearing on the applic for preliminary injunction pursuant to FRCP rule 65(a)(2) & will be advanced on the cts calendar (m)
Mar	2	11	Pltf's MEMO in opposition to defts' M/Dismiss
	4	12	Ctf. of Service of pltf's 1st interrogs. & req. for production to defts.
	4	13	MOTION to shorten time for defts. to resp to pltf's 1st interrogs. & req. for production, fld. by pltf.
	8	14	Defs' Memo. of Law in Opp. to Pltf's M/for a Preliminary Injunct.
	8	15	ORDERED: Defs' M/to Dismiss is denied; Pltf's M/to Shorten Time to Resp. to Interrogs is denied. (m)
	8	16	ORDERED: Disc. cutoff 5/7/82; P/T conf. 5/21/82; N/J Trial during wks. of June 7, 14 and 21, 1982. (m)
	18	17	ANSWER: fld by defts.
Apr	2	18	Pltf's 1st. Interrogs. and Reqs. for Prod. of Docs.
	7	19	Cert. of Service of Interrogs. and Req. for Prod. of Docs.
	8	20	Not/taking depos. April 29, 1982: David Carr, at 10:00 AM, in St. Petersburg Haven Poe, at 11:30 AM in St. Petersburg Dr. H. A. Moore, at 2:00 PM in St. Petersburg
May	3	21	Defs' M/for Ext. of Time for Disc.
	6	22	Depo of Haven Poe (4/29/82)
	6	23	Depo of David Carr (4/29/82)
	6	24	ORDERED: The M/for Ext. of Time for Disc. is granted; Disc. is ext. until 5/17/82. (m)
	7	25	Def's M/for Appt. of Process Server.
	7	26	Not. of Taking Depos of Mili Lamas and Dennis Healey (5/13/82)
	7	27	Depo of Helen A. Moore (4/29/82)
	7	28	M/for Appt. of Process Server-GRANTED (TGW)
	10	29	Pltf's Objects. to Def. Hills. Co.'s 1st Interrogs. and Reqs. for Prod. of Docs.
	12	30	Not. of Re-setting P/T Conf. (5/20/82 at 3 PM)
	12	31	Def. Hills. Co.'s M/to Compel.

	12	32	Memo. in Supp. of M/to Compel.
	17	33	Deft's First Interrogs. & Requests for production of documents & Pltf's Objections an responses
	20		PROCEEDINGS: Pretrial conference in open court Case not to be tried before 6/14/82; briefs, FOF & COL due 6/2/82; ELT 1½ days R-82
	21	34	Pltf's Statement Regarding Proposed P/T Stip.
	21	35	Depo of Helen A. Moore, M.D. (4/29/82)
	21	36	Depo of David Carr (4/29/82)
	21	37	Depo of Haven Poe (4/29/82)
	*19	38	P/T Stip. filed.
	24	39	P/T Order filed.
	26	40	Pltf's Suppl. Resp. to Def's 1st Interrogs. and Reqs. for Prod. of Docs.
1982			
Jun	2	41	Pltf's Trial Memo.
	2	42	Pltf's P/T Proposed Findings of Fact and Conclusions of Law.
	2	43	Def's Trial Brief.
	25	44	NOTICE, re-setting NJ Trial for term beg. 7-6-82 before WJC ctc
	28	45	NOTICE filed by Def.
	29	46	MOTION to Reschedule trial by deft. Hillsb. Co.
July	2	47	MEMO in support of M/reschedule, fld.
	2	48	ORDERED: M/to Resched. is granted; This cause is reset for Status Conf. 7/29/82 at 10 AM; Trial is resched. for 9/6/82. (m)
Sep	16		Non-jury trial: Pltf's opening statement; deft defer opening; Pltf's witnesses: Milli Lamas; Dennis Healey; David Michael Carr; Helen A. Moore; Haven Poe; Milli Lamas (recall); Pltf's ex. #'sl-9,11-22 rec'd in evidence; Pltf rests; Deft County' opening statement; Deft Health Dept endorses opening of Deft County; Deft's witness Donald S. Kwalick; Janice K. Platt; Joseph Kotvas; Jerry Bowmer; Fred Arthur Anderson; Paul J. Schmidt; Frank C. Coleman; Herbert W. Smith R-83
	17		PROCEEDINGS: non-jury trial resumed; Deft's witness: Edward Atkins; Closing args of counsel; Matter taken under advisement R-83
Nov	1	49	OPINION filed. R/83
	1	50	FINAL JUDGMENT: Sec. 7 of Hills. Co. Ord. 80-12 and Sec. 4 of the Rules and Regs. Pursuant to Hills. Co. Ord. 80-12 are invalid in that they impose an impermissible burden on interstate commerce, and the Defs. and their agents and

		employees are hereby enjoined from enforcing or attempting to enforce them; As to the other claims of Pltf. Automated Med. Labs., Inc., Judg. is entered in favor of the Defs Hills. Co., Fla. and Hills. Co. Health Dept., and Pltf. shall take nothing. R/83
24	51	NOTICE OF APPEAL from final judgment entered 11/1/82 by pltf; CC of docket entries notice of appeal and appeal transmittal letter forwarded to 11th Circuit; copies of all the above forwarded to all counsel of record along with appeal info sheet sent to counsel for appellant.
1983		
Jan 3	52	TRANSCRIPT of trial proceedings beginning 9/16/82, Vol. I.
3	53	TRANSCRIPT of trial proceedings, vol. II.
3	54	TRANSCRIPT of trial proceedings, vol. III.
14		ENTIRE RECORD SENT TO USCA, ATLANTA, GA.
*		
Nov30'82	55	Deft Hillsborough County's NOTICE OF CROSS APPEAL
Jan31'83	—	Supplement Record sent to USCA, Atlanta
03/12/84	56	TRANSMITTAL LETTER dated 3/8/84 from USCA indicating that Cert. copy of USCA Judgment, Court's opinion, 2 vol. of original record on appeal and 1 box of original exhibits were being returned. Acknowledged by gg.
03/12/84	57	JUDGMENT (USCA): It is now here ordered and holding by this Court that the Judgment of the District Court finding Section 7 of Ordinance 80-12 and §4 of the rules and regulations invalid is AFFIRMED; the Judgment finding the remaining sections of County Ordinances 80-11 and 80-12 and implementing rules and regulations valid is REVERSED; It is further ordered that defendants-appellees pay to plaintiff-appellant the costs on appeal to be taxed by the Clerk of this Court. ISSUED AS MANDATE 3/8/84. Judgment entered by USCA 1/16/84. Microfilm roll #86; document #2102
03/12/84	58	OPINION of USCA: Affirmed in part, reversed in part. (per Judgment #57 above); Microfilm roll #86; document #2103.

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA

CASE NO. 81-1161-CIV-WC

COMPLAINT
(INJUNCTIVE RELIEF SOUGHT)

AUTOMATED MEDICAL LABORATORIES, INC.,
Plaintiff,

-vs-

HILLSBOROUGH COUNTY, FLORIDA and
HILLSBOROUGH COUNTY HEALTH DEPARTMENT,
Defendants.

The plaintiff, by way of complaint against the defendants, states:

STATEMENT OF CLAIM

1. This is a civil action by Automated Medical Laboratories, Inc. ("Automated") against Hillsborough County, Florida ("County"), and the Hillsborough County Health Department ("County Health Department") seeking a declaratory judgment and injunctive relief.

THE PARTIES, JURISDICTION AND VENUE

2. Automated is a corporation duly organized and existing pursuant to the laws of Florida, and having its principal place of business in the City of Miami, State of Florida.

3. The County is a political subdivision of the State of Florida existing pursuant to the Florida Constitution, art. 8, §1, and governed by the Board of County Commissioners of Hillsborough County, Florida (the "Commissioners"), pursuant to the Florida Constitution art. 8, §1(e) and Fla. Stat. §§125.001 *et seq.*

4. The County Health Department is an agency of the County existing pursuant to Fla. Stat. §154.01.

5. This Court has subject matter jurisdiction of this action pursuant to 28 U.S.C. §1331 (federal question), 28 U.S.C. §1343 (civil rights), 42 U.S.C. §1983 (civil rights), 28 U.S.C. §2201 (declaratory judgment), and the principles of pendent and ancillary jurisdiction.

6. The acts, omissions and transactions herein complained of occurred in substantial part within the Middle District of Florida; venue lies in the Middle District of Florida pursuant to 28 U.S.C. §1391.

FACTUAL BACKGROUND

7. Automated maintains and operates, and has maintained and operated at all times relevant hereto, through its wholly owned subsidiary, Tampa Plasma Corporation, a plasmapheresis facility located at 1502 West Kennedy Boulevard, Tampa, Florida 33606.

8. Plasmapheresis is a procedure whereby, during a single process, blood is removed from a donor, the plasma is removed from the whole blood, and the red blood cells are returned to the donor.

9. Automated collects plasma from human donors who are reimbursed for their time and effort expended during the donation procedure.

10. The plasma collected by Automated is intended, used or sold by Automated solely as source material for further manufacture into pharmaceutical products.

11. The United States Food and Drug Administration ("FDA") of the United States Department of Health and Human Services has issued regulations, contained in 21 CFR Subchapter F - Biologics, which establish, *inter alia*, standards governing, and procedures for the inspection of, facilities engaging in the process of plasmapheresis.

12. In particular, 21 CFR Part 601 sets forth the prerequisites to, and the procedure to be followed in, obtaining both

"establishment" and "product" licenses; 21 CFR Part 606 sets forth regulations pertaining to good practices for the manufacturing of blood and blood components; 21 CFR Part 607 requires establishment registration and product listing for manufacturers of human blood and blood products; and 21 CFR Part 640 sets forth additional standards for human blood and blood products.

13. Automated is subject to and in compliance with the requirements set forth in the FDA regulations contained in 21 CFR Subchapter F - Biologics.

14. On November 26, 1980, the Commissioners passed Ordinance 80-11 ("Ordinance 80-11") relating to the licensing of "Blood Plasma Donor Centers," and providing that any facility performing plasmapheresis on paid donors must be licensed by the Commissioners, [§1(1)], or face prosecution and penalty, [§2(6)]. Ordinance 80-11 provides further that to obtain the required license, an applicant must first possess a valid permit, [§2(1)]. To obtain the permit, an applicant must furnish to the defendant County Health Department the names and residential and mailing addresses of every employee of his facility, [§2(1)](a)(1)], a list and description of the equipment and facilities of the business, [§2(1)(a)(2)], and "such other information deemed necessary" by the County Health Department, [§2(1)(a)(3)]. In addition, the applicant must allow the County Health Department reasonable and continuing access to the facility for purposes of inspection [§2(1)(a)(4)]. The County Health Department must then forward all of the information provided by the applicant to the Commissioners, "together with the recommendation of the...County Health Department and other pertinent information deemed advisable," [§2(3)]. The Commissioners then, upon notice to the applicant and to the County Health Department, shall, in an open, public meeting, issue or deny the permit or continue the matter for just cause, [§2(3)]. A copy of Ordinance 80-11 is attached to this Complaint as Exhibit "A" and made a part hereof.

15. On November 26, 1980, the Commissioners passed Ordinance 80-12 ("Ordinance 80-12") relating to the identification of paid plasma donors, and providing for record keeping and reporting of information by plasmapheresis facilities to the County Health Department. Ordinance 80-12 provides that any person desiring to undergo plasmapheresis for compensation (a

"Commercial Blood Plasma Vendor") at a facility located within Hillsborough County must first apply to the County Health Department for a "plasma vendor identification number" and a "plasma vendor identification card" good for one plasmapheresis facility only, the name of which shall appear on the face of the identification card, [§4]. Ordinance 80-12 provides further that a plasmapheresis facility may perform the plasmapheresis procedure only after the "Commercial Blood Plasma Vendor" has presented his valid identification card, [§6(A)], the facility has ascertained that the "Vendor" has not participated in the procedure in excess of the standards set forth for amounts of blood removed within particular time periods, [§6(C)], the "Vendor" has been examined by a physician and has been issued a certificate of good health as required by the FDA, [§6(D)], and the facility has performed a "breath analysis" on the "Vendor" immediately prior to the extraction and has determined that the "Vendor's" blood does not contain alcohol in excess of .07 percent weight per volume, [§7]. Ordinance 80-12 provides further that each plasmapheresis facility must maintain upon its premises "such testing materials, equipment, supplies and personnel as are approved by the [County Health Department]" for performing breath analysis, [§7]. Ordinance 80-12 requires further that each plasmapheresis facility report daily to the County Health Department the following information for each Vendor on whom the procedure was performed that day: name, address, age, weight, height, sex, plasma vendor identification number, the results of the breath analysis, the results of testing for hepatitis, the amount of whole blood removed, the proportion of blood cells returned, the current hematocrit value, and "any other identifying information as the [County Health] Department may deem necessary," [§6(A) and (B)]. Ordinance 80-12 provides further that each facility shall pay a fee, assessed by the County Health Department and based on the number of procedures performed by the facility, for the purpose of paying the County Health Department's expenses in implementing and maintaining the Commercial Blood Plasma Vendor Identification System, [§6(F)]. Ordinance 80-12 provides further that the County Health Department may make periodic inspections of each facility to determine the existence of any violations of the Ordinance, [§10]. If a violation is found, the Director of the Department may serve upon the facility a citation setting forth the violation and establishing a deadline for its correction, [§11(B)(1)], or the Director may initiate judicial action to enjoin the violation as a nuisance, [§11(B)(3)]. A copy of Ordinance

80-12 is attached to this Complaint as Exhibit "B" and made a part hereof.

16. On or about March 11, 1981, the Commissioners adopted Rules and Regulations Pursuant to Ordinance 80-12 ("regulations"). These regulations require that a person applying for a Commercial Blood Plasma Vendor Identification Card must supply to the County Health Department, *inter alia*, an "affidavit, signed by the applicant and notarized, stating that said applicant has not been detained or treated for acute or chronic alcoholism during the preceding twelve months," [§2(C)]. The regulations require further that "alcohol level testing . . . shall be performed by a qualified operator using a model #900 Smith and Wesson breath analyzer or equipment of equal quality," [§4]. The regulations provide further that duly authorized representatives of the Director of the County Health Department will inspect each plasmapheresis facility "not less than once annually," [§5]. The regulations further provide that in the event it is deemed necessary by "a physician" in the interests of public health, the "County Health Department may require specific tests [to be performed on potential donors] in addition to those reported [sic] and/or an independent physical examination by a physician other than the physician issuing the applicant's Certificate of Good Health," [§6]. The regulations provide further that the "fee" for administration and maintenance of the Commercial Blood Plasma Vendor Identification system to be paid by each plasmapheresis facility shall be the sum of one dollar ($1.00) for each plasmapheresis procedure performed, [§3(C)]. A copy of the regulations are attached to this Complaint as Exhibit "C" and made a part hereof.

COUNT I

(Federal Preemption)

17. Automated repeats and realleges each and every allegation set forth in paragraphs 1 through 16 hereof.

18. The FDA regulations contained in 21 CFR Subpart F require Automated to obtain a license for its establishment and for its product, to register its establishment and to list its product, to meet specified standards with respect to personnel, facilities, and equipment, to maintain extensive written standard operating procedures, to compile voluminous records and to report

specified information to the FDA, to permit inspections by officials of the FDA, to determine the suitability of donors by means of "medical history, tests and such physical examination as appears necessary to [a] qualified licensed physician" prior to performing the procedure, to reject any donor who "appears to be under the influence of any drug, [or] alcohol" or who appears unsuitable for other reasons, to establish a donor identification system, and to obtain each donor's written informed consent.

19. Ordinance 80-11, Ordinance 80-12, and the regulations thereunder purport to regulate subject matter preempted by federal laws and regulations, in particular those regulations contained in 21 CFR Subchapter F.

20. Ordinance 80-11, Ordinance 80-12, and the regulations thereunder are unconstitutional and invalid under the Commerce Clause of the United States Constitution, U.S. Const. art. I, §8, cl. 3, and the Supremacy Clause of the United States Constitution, U.S. Const. art. VI, cl. 2.

COUNT II

(Impermissible Burden on Interstate Commerce)

21. Automated repeats and realleges each and every allegation set forth in paragraphs 1 through 20 hereof.

22. Ordinances 80-11 and 80-12 and the regulations thereunder subject Automated to additional, burdensome and inconsistent or potentially inconsistent requirements regarding licensing, facilities, the compiling and reporting of information, the identification of donors, and the determination of donor suitability. Pursuant to Ordinances 80-11 and 80-12, and the regulations thereunder, Automated must now procure a county permit and license for its facility as well as federal licenses for, and registrations of, its establishment and its product, it must be subject to duplicative and potentially inconsistent standards regarding its facility and equipment, it is subject to duplicative and potentially inconsistent compilation and reporting requirements, and it is subject to inconsistent requirements regarding the determination of donor suitability.

23. The effect of Ordinances 80-11 and 80-12 and the regulations thereunder, by imposing upon Automated extremely

expensive, time consuming, duplicative and unnecessary requirements, will be to decrease dramatically the ability of Automated to collect human plasma for further manufacture into various pharmaceutical products, and will therefore decrease dramatically the availability of these pharmaceutical products manufactured in part from human plasma collected by Automated.

24. These local ordinances and regulations, adopted ostensibly to safeguard the health in Hillsborough County, impose an indirect burden on interstate commerce which is not justified by local need. The federal regulations contained in 21 CFR Subchapter F impose requirements, standards and procedures sufficient to safeguard the health of donors, thus already effecting the local interest as well as the national interest by means of a single set of regulations.

25. Ordinance 80-11, Ordinance 80-12, and the regulations are unconstitutional and invalid under the Commerce Clause of the United States Constitution, U.S. Const. art. I, §8, cl. 3, and the Supremacy Clause of the United States Constitution, U.S. Const. art. VI, cl. 2.

COUNT III

(Deprivation of Rights, Privileges and Immunities)

26. Automated repeats and realleges each and every allegation set forth in paragraphs 1 through 25 thereof.

27. Section 6(F) of Ordinance 80-12, and §3(C) of the regulations require that Automated pay to the County Health Department the sum of one dollar ($1.00) for each plasmapheresis procedure performed.

28. The amount specified is wholly arbitrary and excessive relative to the actual expense which will reasonably be incurred by the County Health Department.

29. The amount specified represents a substantial portion of Automated's income and is a major burden on the survival capability of Automated's business.

30. The acts, omissions and threatened acts on the part of

the County, the Commissioners, and the County Health Department complained of herein constitute a deprivation, under color of state law, of Automated's rights, privileges and immunities secured by the Constitution and laws of the United States within the meaning of 28 U.S.C. §1343(3) and 42 U.S.C. §1983.

COUNT IV

(Deprivation of Equal Protection)

31. Automated repeats and realleges each and every allegation set forth in paragraphs 1 through 30 hereof.

32. Ordinances 80-11 and 80-12 and the regulations arbitrarily apply only to establishments which perform plasmapheresis on paid donors. There is no rational basis for discriminating between such establishments, of which Automated is one, and similar establishments which perform plasmapheresis on uncompensated donors, or those which extract whole blood from donors whether compensated or not.

33. The acts, omissions and threatened acts on the part of the County, the Commissioners and the County Health Department complained of herein, constitute a denial of the equal protection of law in violation of the Fourteenth Amendment to the Constitution of the United States of America.

COUNT V

(Unlawful delegation of police power)

34. Automated repeats and realleges each and every allegation set forth in paragraphs 1 through 33 hereof.

35. Ordinance 80-11 makes the obtaining of a license and permit to operate a plasmapheresis facility conditional upon an applicant's furnishing to the County Health Department unspecified "information deemed necessary" by the County Health Department [§2(1)(a)(3)]. The County Health Department then forwards to the Commissioners its "recommendation" and "other pertinent information deem advisable", [§2(3)]. The Commissioners then have the power to refuse to grant a permit and license on the basis of the County Health Department's information and recommendation, [§2(3)], and anyone engaging

in the operation of a plasmapheresis facility without the required license is subject to prosecution and punishment, [§2(6)].

36. Sections 2(1)(a)(3) and 2(3) of Ordinance 80-11 lack sufficient guidelines to limit the County Health Department's exercise of discretion, they fail to establish standards and tests for the acts of the County Health Department, and they allow the County Health Department to act arbitrarily, capriciously, and with absolute discretion in deciding what additional, unspecified information will be required to be submitted by some or all permit applicants, and in deciding what additional, unspecified information will be forwarded to the Commissioners together with the County Health Department's recommendation regarding a permit application.

37. Sections 2(1)(a)(3) and 2(3) of Ordinance 80-11 constitute unlawful delegations of the police power and of the legislative authority granted to the County and to the Commissioners by Fla. Stat. §381.101.

COUNT VI

(Deprivation of Due Process)

38. Automated repeats and realleges each and every allegation set forth in paragraphs 1 through 37 hereof.

39. Sections 2(1)(a)(3) and 2(3) of Ordinance 80-11 are vague, indefinite and uncertain, they fail to give potential applicants a reasonable opportunity to know what is required, and they fail to provide explicit standards in order to prevent arbitrary and discriminatory decisions with respect to the grant or denial of applications.

40. Sections 2(1)(a)(3) and 2(3) of Ordinance 80-11 violate the potential permit and license applicant's right to due process of law guaranteed by the Fifth and Fourteenth Amendments to the Constitution of the United States and by the Florida Constitution.

COUNT VII

(Unlawful delegation of police power)

41. Automated repeats and realleges each and every allegation set forth in paragraphs 1 through 40 hereof.

42. Ordinance 80-12 requires that each plasmapheresis facility report daily to the County Health Department certain specified information as well as "any other identifying information as the [County Health] Department may deem necessary," [§6(a)(9)]. The County Health Department is empowered to give notice of any act or condition which it deems to be in violation of Ordinance 80-12, [§11], and anyone convicted of a violation of Ordinance 80-12 is punishable by a fine of up to $500 or by imprisonment of up to 60 days or both, [§14].

43. Section 6(A)(9) of Ordinance 80-12 lacks sufficient guidelines to limit the County Health Department's exercise of discretion, it fails to establish standards and tests for the acts of the County Health Department, and it allows the County Health Department to act arbitrarily, capriciously and with absolute discretion in deciding what additional, unspecified information will be required to be submitted by some or all permit applicants, and in deciding what additional, unspecified information will be required to be submitted by some or all plasmapheresis facilities.

44. Section 6(A)(9) of Ordinance 80-12 constitutes an unlawful delegation of the police power and of the legislative authority granted to the County and to the Commissioners by Fla. Stat. §381.101.

COUNT VIII

(Deprivation of Due Process)

45. Automated repeats and realleges each and every allegation set forth in paragraphs 1 through 44 hereof.

46. Section 6(A)(9) of Ordinance 80-12 is vague, indefinite and uncertain, it fails to give facility operators a reasonable opportunity to know what is required, and it fails to provide ex-

plicit standards in order to prevent arbitrary and discriminatory enforcement of the ordinance.

47. Section 6(A)(9) of Ordinance 80-12 violates the facility operator's right to due process of law guaranteed by the Fifth and Fourteenth Amendments to the Constitution of the United States and by the Florida Constitution.

COUNT IX

(County Health Department acts in excess of its authority)

48. Automated repeats and realleges each and every allegation set forth in paragraphs 1 through 47 hereof.

49. Section 6 of the regulations provides that the County Health Department may, if it is deemed necessary by "a physician," "require specific tests [to be performed on potential donors] in addition to those" required by Ordinance 80-12, and may require "an independent physical examination by a physician other than the physician issuing the applicant's Certificate of Good Health."

50. In asserting that it has the authority to require additional tests and physical examinations, the County Health Department is acting in excess of the authority granted to it under Ordinance 80-12 or the laws of the State of Florida by which the County Health Department was created and exists, and the County Health Department is asserting authority that is not granted to it under any law, statute, regulation or ordinance of the County, the State of Florida, or of the United States.

COUNT X

(County Health Department acts in excess of its authority)

51. Automated repeats and realleges each and every allegation set forth in paragraphs 1 through 50 hereof.

52. Section 2(C) of the regulations requires that an applicant for a Commercial Blood Plasma Identification card submit to the County Health Department "an affidavit, signed...and notarized, stating that said applicant has not been detained or treated for acute or chronic alcoholism during the preceding twelve months."

53. In asserting that it has the authority to require such an affidavit, the County Health Department is acting beyond and in excess of the authority granted to it under Ordinance 80-12 or the laws of the State of Florida by which the County Health Department was created and exists, and the County Health Department is asserting authority that is not granted to it under any law, statute, regulation or ordinance of the County, the State of Florida, or of the United States.

COUNT XI

(Deprivation of Due Process)

54. Automated repeats and realleges each and every allegation set forth in paragraphs 1 through 53 hereof.

55. The word "detained" as used in §2(C) of the regulations is vague, ambiguous, uncertain and indefinite, in that no particular type of detention is specified.

56. In requiring such an affidavit, §2(C) of the County Health Department's regulations violates the potential donor's right to due process of law guaranteed by the Fifth and Fourteenth Amendments to the Constitution of the United States and by the Florida Constitution.

COUNT XII

(The Commissioners act in excess of their statutory power)

57. Automated repeats and realleges each and every allegation set forth in paragraphs 1 through 56 hereof.

58. The Commissioners, in enacting Ordinance 80-11, are acting beyond and in excess of the authority granted to them under Fla. Stat. §381.101 and §381.031(1)(h), and the Commissioners are asserting an authority that is not granted to them under any law, statute, regulation, or ordinance of the State of Florida or of the United States.

WHEREFORE, Automated demands judgment against the defendants as follows:

A. With regard to COUNT I, a declaratory judgment that

the subject matter of Ordinances 80-11 and 80-12 and the regulations thereunder is preempted by federal law and regulations, in particular those regulations contained in 21 CFR Subchapter F, and that Ordinances 80-11 and 80-12 and the regulations thereunder violate the Commerce and Supremacy Clauses of the Constitution of the United States and are therefore wholly without force and effect, illegal, null and void, and unconstitutional, and a preliminary and permanent injunction preventing the County and County Health Department from enforcing or attempting or threatening to enforce said Ordinances or regulations;

B. With regard to COUNT II, a declaratory judgment that Ordinances 80-11 and 80-12 and the regulations thereunder constitute an impermissible burden on interstate commerce not warranted or justified by legitimate local need, and that Ordinances 80-11 and 80-12 and the regulations thereunder violate the Commerce and Supremacy Clauses of the Constitution of the United States and are therefore wholly without force and effect, illegal, null and void, and unconstitutional, and a preliminary and permanent injunction preventing the County and County Health Department from enforcing or attempting or threatening to enforce said Ordinances or regulations;

C. With regard to COUNT III, a declaratory judgment that the requirement in §6(F) of Ordinance 80-12, and §3(C) of the regulations, that Automated pay to the County Health Department the sum of one dollar ($1.00) for each plasmapheresis procedure performed is wholly arbitrary, excessive and constitutes a deprivation, under color of state law, of Automated's rights, privileges and immunities secured by the Constitution and laws of the United States within the meaning of 28 U.S.C. §1343(3) and 42 U.S.C. §1983, and that §6(F) of Ordinance 80-12 and §3(C) of the regulations are therefore wholly without force and effect, illegal, null and void, and unconstitutional, and a preliminary and permanent injunction preventing the County and County Health Department from enforcing or attempting or threatening to enforce said sections of Ordinance 80-12 and the regulations;

D. With regard to COUNT IV, a declaratory judgment that Ordinances 80-11 and 80-12 and the regulations constitute a denial of Automated's right to equal protection of the law in violation of the Fourteenth Amendment to the Constitution of

the United States, and are therefore wholly without force and effect, illegal, null and void, and unconstitutional, and a preliminary and permanent injunction preventing the County and County Health Department from enforcing or attempting or threatening to enforce said Ordinances or regulations;

E. With regard to COUNT V, a declaratory judgment that Sections 2(1)(a)(3) and 2(3) of Ordinance 80-11 constitute unlawful delegations of the police power and of the authority granted to the County and Commissioners by Fla. Stat. §381.101, and are therefore wholly without force and effect, illegal, null and void, and unconstitutional, and a preliminary and permanent injunction preventing the County and County Health Department from enforcing or attempting or threatening to enforce said sections of Ordinance 80-11;

F. With regard to COUNT VI, a declaratory judgment that Sections 2(1)(a)(3) and 2(3) of Ordinance 80-11 are vague, indefinite, uncertain and constitute a denial of Automated's right to due process of law in violation of the Fifth and Fourteenth Amendments to the Constitution of the United States and of the Florida Constitution, and are therefore wholly without force and effect, illegal, null and void, and unconstitutional, and a preliminary and permanent injunction preventing the County and County Health Department from enforcing or attempting or threatening to enforce sections 2(1)(a)(3) and 2(3) of Ordinance 80-11;

G. With regard to COUNT VII, a declaratory judgment that section 6(A)(9) of Ordinance 80-12 constitutes an unlawful delegation of the police power and of the authority granted to the County and Commissioners by Fla. Stat. §381.101, and is therefore wholly without force and effect, illegal, null and void, and unconstitutional, and a preliminary and permanent injunction preventing the County and County Health Department from enforcing or attempting or threatening to enforce section §6(A)(9) of Ordinance 80-12;

H. With regard to COUNT VIII, a declaratory judgment that section 6(A)(9) of Ordinance 80-12 is vague, indefinite, uncertain and constitutes a denial of due process of law in violation of the Fifth and Fourteenth Amendments to the Constitution of the United States and of the Florida Constitution, and is therefore wholly without force and effect, illegal, null and void,

and unconstitutional, and a preliminary injunction preventing the County and County Health Department from enforcing or attempting or threatening to enforce section 6(A)(9) of Ordinance 80-12;

I. With regard to COUNT IX, a declaratory judgment that §6 of the regulations issued by the County Health Department is beyond and in excess of the authority granted to the County Health Department by Ordinance 80-12, and is therefore wholly without force and effect, illegal, null and void, and unconstitutional, and a preliminary and permanent injunction preventing the County and County Health Department from enforcing or attempting or threatening to enforce section 6 of the regulations;

J. With regard to COUNT X, a declaratory judgment that §2(C) of the regulations issued by the County Health Department are beyond and in excess of the authority granted to the County Health Department by Ordinance 80-12, and is therefore wholly without force and effect, illegal, null and void, and unconstitutional, and a preliminary and permanent injunction preventing the County and County Health Department from enforcing or attempting or threatening to enforce section 2(C) of the regulations;

K. With regard to COUNT XI, a declaratory judgment that the use of the word "detained" in §2(C) of the regulations is vague, ambiguous, uncertain and indefinite, and constitutes a denial of the potential donor's right to due process of law, all in violation of the Fifth and Fourteenth Amendments to the Constitution of the United States and of the Florida Constitution, and is therefore wholly without force and effect, illegal, null and void, and unconstitutional, and a preliminary and permanent injunction preventing the County and County Health Department from enforcing or attempting or threatening to enforce §2(C) of the regulations;

L. With regard to COUNT XII, a declaratory judgment that in enacting Ordinance 80-11, the Commissioners acted beyond and in excess of their statutory authority, and that Ordinance 80-11 is therefore wholly without force and effect, illegal, null and void, and unconstitutional, and a preliminary and permanent injunction preventing the County and County Health Department from enforcing or attempting or threatening to enforce Ordinance 80-11;

M. Such other and further relief as may to this Court seem just and proper.

Dated: December 14, 1981

GOLDSTEIN GOLDMAN KESSLER
& UNDERBERG
Attorneys for Automated Medical
Laboratories, Inc.

By:_____
Larry A. Stumpf
One Biscayne Tower, Suite 1740
Two South Biscayne Boulevard
Miami, Florida 33131
(305) 358-4930

Exhibit A 11/26/80

ORDINANCE #80-11

AN ORDINANCE AMENDING THE HILLSBOROUGH COUNTY OCCUPATIONAL LICENSE ORDINANCE #80-6; PROVIDING A SPECIFIC CLASSIFICATION FOR BLOOD PLASMA DONOR CENTERS AND SETTING THE OCCUPATIONAL LICENSE TAX AT $225.00; PROVIDING FOR A PERMIT, AND PROVIDING AN EFFECTIVE DATE

Section 1. Hillsborough County Ordinance 80-6 is amended to add Section 56.01 to read as follows:

Section 56.01 BLOOD PLASMA DONOR CENTERS

(1) Every person or association of persons conducting, carrying on or otherwise engaging in the business (occupation) of a Blood Plasma Donor Center as defined below, shall pay a license tax of $225.00.

(2) "Blood Plasma Donor Center" is defined as any facility, laboratory, or place of business which performs the procedure known as "plasmapheresis" on commercial Blood Plasma Vendors and which compensates said Blood Plasma Vendors by payment of money or other thing of value.

Section 2. Hillsborough County Ordinance 80-6 is amended to add Section 57.01 to read as follows:

Secton 57.01 — BLOOD PLASMA DONOR CENTERS; COUNTY PERMIT REQUIRED; PENALTY —

(1) No license to engage in the occupation of a Blood Plasma Donor Center or any other business entity for which a license is required by Section 56.01 of this Ordinance, shall be issued to any person or association of persons not possessing a valid permit issued by the Hillsborough County Board of County Commissioners (Board). Said permit shall be issued in triplicate with the original being given to the applicant, one copy being retained by the Hillsborough County Health Department, and one copy being retained by the Tax Collector. All permits and licenses issued under the provisions of this Ordinance shall be non-transferable. No permit shall be issued by the Board until the following conditions have been fulfilled:

(a) The applicant for the permit has:

1. Furnished the Hillsborough County Health Department (upon forms provided) with the name and mailing and residential addresses for all non-owner and owner personnel employed with the place of business for which the related license tax is applicable pursuant to Section 56.01 of this Ordinance.

2. Furnished to the Hillsborough County Health

Department (upon forms provided) a list and description of the equipment and facilities of the place of business for which related license tax is applicable pursuant to Section 56.01 of this Ordinance.

3. Furnished to the Hillsborough County Health Department (upon forms provided) such other information as deemed necessary by the Hillsborough County Health Department.

4. Allowed the Hillsborough County Health Department reasonable and continuing access to the premises of the Blood Plasma Donor Center or other business entity concerned with the permit sought by the applicant; said access being granted for purposes of allowing the Hillsborough County Health Department opportunity to inspect the premises.

(2) The possessor of any permit issued by the Board shall, within thirty (30) days of an event or occurrence that causes a change to the information given to the Hillsborough County Health Department pursuant to sub-sections 57.01(1)(a)1, 57.01(1)(a)2, and 57.01(1)(a)3 of this Ordinance, advise the Hillsborough County Health Department (in writing) of such change.

(3) The Hillsborough County Health Department shall, within fifteen (15) days of receiving a completed application for a permit as described by this Section, forward to the Board all such information furnished by the permit applicant; together with the recommendation of the Hillsborough County Health Department and other pertinent information deemed advisable. The Board shall consider the information submitted to it in open, public meeting after notice to the permit applicant and the Hillsborough County Health Department; whereupon the Board shall either issue the permit, continue the matter for just cause, or deny the permit.

(4) Blood Plasma Donor Centers or other business entities issued a permit pursuant to the provisions of this Section shall automatically be re-permitted annually by the Board unless such re-permitting is denied by the Board for just cause after notice and opportunity to be heard. The County Tax Collector shall be notified when re-permitting is denied by the Board.

(5) Every licensee comprehended by Section 56.01 of this Ordinance shall at all times while engaging in the occupation for which licensed, display at the applicable place of business both the license thereby required and the permit required by this Section. Failure or refusal to do so shall be prima facie evidence of engaging in such occupation without a license.

(6) Anyone engaging in any occupation comprehended by Section 56.01 of this Ordinance without a license and the permit required by this Section or who shall obtain any such permit or license by fraud or deceit shall, be subject to prosecution and punishment as described in Section 7.02 of this Ordinance.

Section 3. This Ordinance shall become effective immediately upon acknowledgement from the Secretary of State that it has been properly filed as required by law.

STATE OF FLORIDA)
COUNTY OF HILLSBOROUGH)

I, JAMES F. TAYLOR, Clerk of the Circuit Court and Ex Officio Clerk of the Board of County Commissioners of Hillsborough County, Florida, do hereby certify that the above and foregoing is a true and correct copy of an Ordinance adopted by the Board in its regular meeting of November 26, 1980, as the same appears of record in Minute Book 76 of the Public Records of Hillsborough County, Florida.

WITNESS my hand and official seal this 5th day of December, 1980.

JAMES F. TAYLOR, JR., CLERK
BY: _____
Deputy Clerk

Exhibit B 11/26/80

ORDINANCE #80-12

AN ORDINANCE OF HILLSBOROUGH COUNTY, FLORIDA; RELATING TO IDENTIFICATION OF COMMERCIAL BLOOD PLASMA VENDORS: DEFINING TERMS; REQUIRING BLOOD PLASMA VENDOR IDENTIFICATION CARDS; ESTABLISHING PROCEDURES FOR OBTAINING CARDS; PROVIDING FOR RECORD KEEPING AND REPORTING; SETTING FEES; REQUIRING BREATH ANALYSIS; REQUIRING REPORTING OF COMMUNICABLE DISEASE; PROVIDING FOR ADMINISTRATION; PROVIDING FOR ENFORCEMENT AND INSPECTION; REQUIRING NOTICE; SPECIFYING PENALTY FOR VIOLATIONS; PROVIDING FOR SEVERABILITY; PROVIDING AN EFFECTIVE DATE.

WHEREAS, Section 125.01(1)(w), Florida Statutes allows the Board of County Commissioners of Hillsborough County, Florida, to perform any acts not inconsistent with law which are in the common interest of the people of the County, and exercise all powers and privileges not specifically prohibited by law; and

WHEREAS, Section 125.01(1)(t), Florida Statutes allows the Board of County Commissioners of Hillsborough County, Florida to adopt ordinances necessary for the exercise of its power; and

WHEREAS, the Hillsborough County Board of County Commissioners finds and determines that the interests of the public health mandate the monitoring of the plasmapheresis procedure within Hillsborough County; and

WHEREAS, Section 381.311, Florida Statutes requires local health officials to enforce provisions of local ordinance relating to the public health.

NOW, THEREFORE, BE IT ORDAINED BY THE BOARD OF COUNTY COMMISSIONERS OF HILLSBOROUGH COUNTY, FLORIDA, IN REGULAR MEETING ASSEMBLED THIS _____ DAY OF _____, 1980.

Section 1. Short Title — This ordinance shall be known as the "Commercial Blood Plasma Vendor Identification Ordinance".

Section 2. Statement of Purpose — The purpose of this Ordinance is to provide a system for the registration and identification of and the gathering of medical data applicable to Commercial Blood Plasma Vendors as being in the common interest

of the health of the people of Hillsborough County.

Section 3. Definitions

(A) "Commercial Blood Plasma Vendor" is defined as an individual who sells, barters, or exchanges for monetary consideration, the liquid portion of his or her blood (plasma), through the plasmapheresis process.

(B) "Plasmapheresis" is defined as the procedure whereby whole blood is removed from a Commercial Blood Plasma Vendor by venipuncture (or phlebotomy) the plasma is separated therefrom, and the blood cells returned to the Vendor.

(C) "Plasmapheresis Facility" is defined as any facility, laboratory, or place of business where Commercial Blood Plasma Vendors participate in the plasmapheresis process.

(D) "Department" is defined as the Hillsborough County Health Department.

Section 4. Plasma Donor Identification Card. All Commercial Blood Plasma Vendors within Hillsborough County are required to obtain a valid plasma vendor identification card from the Department. The card shall contain identifying information, as required by the Department, and a number, unique to the Vendor. Only one (1) card and one (1) number shall be issued to each Vendor. The identification card shall be good for one (1) plasmapheresis facility only, the name of which shall appear on the face of the identification card.

Section 5. Procedure

(A) Each prospective Commercial Blood Plasma Vendor shall, before undergoing plasmapheresis, make application to the Department, on a form to be provided by the Department, for a plasma vendor identification number and a plasma vendor identification card. The Commercial Blood Plasma Vendor must provide such identifying information as is deemed necessary by the Department and shall tender to the Department a fee of no more than ten dollars ($10.00) which fee shall fairly reflect the Department's costs for issuance of the plasma vendor identification card. Identification cards issued under the provisions of this Ordinance shall be valid for six (6) months from the date of issue.

(B) In the event a plasma vendor identification card is lost, stolen, or mutilated, a duplicate card will be issued, which card shall be valid for the same period as the original card, and shall only be good for the same plasmapheresis facility as the original card. The fee for such duplicate shall be no more than three dollars ($3.00).

Section 6. Record-keeping

(A) No plasmapheresis facility within Hillsborough County may perform the plasmapheresis process on a Commercial Blood Plasma Vendor until said Vendor presents the plasmapheresis facility with a valid plasma Vendor identification card as required by Section 4 of this Ordinance. The plasmapheresis facility shall keep accurate records of each plasmapheresis procedure performed by it, which shall include:

(1) The date of the plasmapheresis procedure;
(2) The name, address, age, weight, height and sex of the Vendor;
(3) The plasma Vendor identification number of the Vendor;
(4) The results of breath analysis of the Vendor as required by Section 7 of this Ordinance;
(5) The amount of whole blood, not including anticoagulant, removed from the Vendor during the plasmapheresis procedure;
(6) The proportion of the blood cells successfully returned to the Vendor at the time of each procedure;
(7) The results of testing for hepatitis;
(8) The current hematocrit value
(9) Any other identifying information as the Department may deem necessary.

(B) All plasmapheresis facilities within Hillsborough County shall provide the aforementioned information daily to the Department, in writing, who shall compile and maintain such information and give prompt notification of any violation of this Ordinance or of the rules and regulations promulgated hereto.

(C) Prior to beginning the plasmapheresis procedure upon any Commercial Blood Plasma Vendor, the plasmapheresis facility shall ascertain that said Vendor has not participated in the plasmapheresis procedure in excess of the amounts listed below within the times indicated:

(1) The amount of whole blood, not including anticoagulant, removed from a Vendor during the plasmapheresis procedure in any forty-eight (48) hour period shall not exceed one thousand (1,000) milliliters unless the Vendor's weight is one hundred seventy-five (175) pounds or greater, in which case the amount of whole blood, not including anticoagulant removed from the Vendor during the plasmapheresis procedure, in any forty-eight (48) hour

period shall not exceed one thousand two hundred (1,200) milliliters.

(2) The amount of whole blood, not including anticoagulant, removed from a Vendor during the plasmapheresis procedure, within a seven-day period shall not exceed two thousand (2,000) milliliters, unless the Vendor's weight is one hundred seventy-five (175) pounds or greater, in which case the amount of whole blood, not including anticoagulant, removed from the Vendor during the plasmapheresis procedure, within a seven-day period shall not exceed two thousand four hundred (2,400) milliliters.

(3) During the plasmapheresis procedure, no more than five hundred (500) milliliters of whole blood shall be removed from a Vendor at one time unless the Vendor's weight is one hundred seventy-five (175) pounds or greater, in which case no more than six hundred (600) milliliters of whole blood shall be removed from the Vendor at one time.

(D) No plasmapheresis facility within Hillsborough County may perform the plasmapheresis process on a Commercial Blod [sic] Plasma Vendor until said Vendor has been examined by a physician and issued a certificate of good health as required by the regulations of the Food and Drug Administration (FDA), of the United States Department of Health and Human Services.

(E) The Department shall keep all records in a manner which protects the rights of individuals to the confidentiality of their medical records. The disclosure of the identity of, or other information relating to Commercial Blood Plasma Vendors is expressly prohibited, except as such disclosure is directly related to and necessary for enforcement of this Ordinance or as is required by law.

(F) The Department shall assess a fee upon each plasmapheresis facility for the purpose of paying the expenses which the Department shall incur, both direct and indirect, in the implementation and maintenance of the Commercial Blood Plasma Vendor Identification System. The fee shall be based upon the number of plasmapheresis procedures performed by the plasmapheresis facility and shall be payable monthly by the facility upon receipt of an invoice from the Department. Said fee shall not exceed the amount of one dollar ($1.00) for each plasmapheresis procedure which has been performed by the facility, and the total of fees collected shall not exceed the cost to the Department of administering and maintaining the Com-

mercial Blood Plasma Vendor identification system.

Section 7. Breath Analysis — It shall be unlawful for any plasmapheresis facility in Hillsborough County to extract whole blood or any of its products from a Commercial Blood Plasma Vendor unless, immediately prior to said extraction, the facility shall analyze the breath of the Commercial Blood Plasma Vendor and determine from such analysis that the blood of the Commercial Blood Plasma Vendor does not contain alcohol in excess of 0.07 per cent, weight per volume. For the purpose of performing the required breath analysis, each plasmapheresis facility in Hillsborough County shall maintain upon the premises thereof such testing materials, equipment, supplies, and personnel as are approved by the Department.

Section 8. Reporting of Communicable Disease — Any plasmapheresis facility or employee thereof who shall discover that the Vendor evidences veneral disease, or other communicable disease shall immediately submit to the Hillsborough County Health Department a confidential report setting forth the nature of the disease and the name, address commercial blood plasma vendor identification number, and other information sufficient to identify and locate the Vendor.

Section 9. Prohibited Acts — It shall be unlawful for any person to obtain or attempt to obtain more than one plasma vendor identification card or more than one plasma vendor identification number, or for any person to attempt to utilize a vendor identification card or vendor identification number of another individual, or for any person to provide false information to a plasmapheresis facility or to the Hillsborough County Health Department in connection with the application for a Vendor identification card or identification number or in connection with any plasmapheresis procedure.

Section 10. Enforcement and Inspection — It shall be the responsibility of the Director of the Hillsborough County Health Department or his duly authorized representative to enforce the provisions of this Ordinance throughout Hillsborough County and the Director may promulgate rules and regulations necessary to carry out the provisions of this Ordinance. The Hillsborough County Health Department may make periodic inspections of each plasmapheresis facility in Hillsborough County for the purpose of determining the existence of any violation of this Ordinance.

Section 11. Denial, Suspension or Revocation of Identification Card.

A. If the Director of the Hillsborough County Health

Department determines that an individual has violated a provision of this Ordinance, he may deny, suspend, or revoke any Vendor identification card or identification number, according to the following criteria:

(1) For a violation by a person who is not a registered Commercial Blood Plasma Vendor, a disqualification of that person from becoming a registered Vendor for a period not exceeding ninety (90) days for each violation.

(2) For the first violation by a registered Commercial Blood Plasma Vendor, suspension of the Vendor identification card and number and all the privileges incident thereto for a period not exceeding ninety (90) days.

(3) For the second violation by a registered Commercial Blood Plasma Vendor, suspension of the Vendor identification card and number and all the privileges incident thereto for a period not exceeding one (1) year.

(4) For the third violation by a registered Commercial Blood Plasma Vendor, suspension of the Donor identification card and number and all the privileges incident thereto for a period not exceeding five (5) years, or permanent revocation of the Vendor identification card and registration number and all the privileges incident thereto.

(B) If the Director of the Hillsborough County Health Department or his designee shall determine that a violation of this Ordinance or of any regulation promulgated hereunder has occurred, the Director may take one or more of the following actions:

(1) Service upon the person or facility in violation of a citation setting forth the violation and establishing a time within which such violation must be corrected.

(2) Initiation of a procedure for the denial, revocation, suspension, limitation, of any Commercial Blood Plasma Vendor identification card.

(3) The initiation of a judicial procedure for injunctive action against any individual or organization violating this ordinance, it being hereby declared that the performance of the plasmapheresis procedure on any Commercial Blood Plasma Vendor in violation of this Ordinance or any regulation promulgated hereunder is a nuisance inimical to the public health, welfare, and safety.

(4) Whenever the Director of the Department shall have determined the existence of a violation of

this Ordinance which constitutes an immediate threat to the health, safety, or welfare of a Commercial Blood Plasma Vendor, a potential recipient of blood or plasma, or the public, and such condition cannot or will not be immediately corrected, the Director of Public Health may order the immediate closing of such plasmapheresis facility and initiate judicial proceedings seeking injunctive relief to accomplish said purpose until such time as the threat is found no longer to exist.

(C) Whenever the Director of the Hillsborough County Health Department or his duly authorized representative believes that there has been a violation of the provisions of this Ordinance, he shall serve notice of such violation in writing to the party responsible for such violation. The notice shall specify the violation and shall be deemed to be properly served and binding upon the party responsible, if a copy is served personally or served by certified mail, or if after diligent search and inquiry the party responsible for the violation cannot be found or served by personal service or certified mail, a copy of the notice is published once during each week for four (4) consecutive weeks in a newspaper of general circulation within Hillsborough County. The newspaper shall meet such requirements as prescribed by law for such purpose. Such notice shall inform the party to whom it is directed of the right to apply to the Hillsborough County Board of County Commissioners for a hearing and review of the matters specified in the notice.

Section 13. Appeal — Any person aggrieved by a decision of the Department made under the provisions of this Ordinance shall have the right to appeal such decision to the Hillsborough County Board of County Commissioners (Board). Said appeal must be in writing and received by the Board no later than ten (10) days from the date of the decision to be reviewed. The Board shall set such appeal for hearing at the earliest possible date, and cause notice thereof to be given to the appellant and the Director of the Hillsborough County Heatlh Department. The Board shall hear and consider all facts material to the appeal and render a decision promptly. The Board may affirm, reverse, or modify the action or decision appealed from providing that the Board shall not take any action which conflicts or nullifies any of the provisions of this Ordinance. The Board shall specifically state in its decision the date by which compliance must be made. The decision of the Board shall be final, and no rehearing or reconsideration shall be considered. Any party aggrieved by any decision of the Board on appeal taken to it, may apply to the Circuit Court of Hillsborough County for a review by writ of certiorari in accordance with the applicable Florida appellate rules.

Section 14. Penalty — A conviction for violation of the provisions of this Ordinance shall be punishable by a fine not to exceed five hundred dollars ($500.00) or by imprisonment in the County jail for a term not to exceed sixty (60) days or both such fine and imprisonment, as provided in Section 125.69, Florida Statutes.

Section 15. Federal Regulations — The regulations of the Commissioner of the Food and Drug Administration of the United States Department of Health and Human Services, as they may be amended from time to time concerning plasmapheresis and source plasma (human) currently appearing at 21 CFR Part 640, Subpart G, Section 640.60 et seq, are here incorporated by reference and shall be a part of this Ordinance as though set forth herein verbatim.

Section 16. Severability — If any section, subsection, sentence, clause, provision or part of this Ordinance shall be held invalid for any reason, the remainder of this Ordinance shall not be affected thereby, but shall remain in full force and effect.

Section 17. Effective Date — This Ordinance shall take effect ninety (90) days after filing with the Secretary of State as provided by law.

STATE OF FLORIDA)
COUNTY OF HILLSBOROUGH)

I, JAMES F. TAYLOR, Clerk of the Circuit Court and Ex Officio Clerk of the Board of County Commissioners of Hillsborough County, Florida, do hereby certify that the above and foregoing is a true and correct copy of an Ordinance adopted by the Board in its regular meeting of November 26, 1980, as the same appears of record in Minute Book 76 of the Public Records of Hillsborough County, Florida.

WITNESS my hand and official seat [sic] this 5th day of December, 1980.

JAMES F. TAYLOR, JR. CLERK
BY: _____
Deputy Clerk

Exhibit C

3/5/81

RULES AND REGULATIONS PURSUANT TO HILLSBOROUGH COUNTY ORDINANCE #80-12

Section 1. — Purpose

These Rules and Regulations are adopted to establish procedures for the monitoring of the plasmapheresis process within Hillsborough County, and the issuance of Commercial Blood Plasma Vendor Identification Cards by the Hillsborough County Health Department, under the Authority of Hillsborough County Ordinance 80-12.

Section 2. — Identification

Before being issued a Commercial Blood Plasma Vendor Identification Card pursuant to Hillsborough County Ordinance 80-12, each applicant shall furnish to the Hillsborough County Health Department:

A. One of the following items of positive identification:
   1. A Social Security card exhibiting the applicant's signature;
   2. A Hillsborough County voter registration card exhibiting the applicant's signature;
   3. A selective service identification card exhibiting the applicant's signature;
   4. A valid driver's license exhibiting the applicant's photograph and signature;
   5. A United States passport exhibiting the applicant's photograph and signature;
   6. Discharge documents from the United States military service exhibiting the applicant's signature.

B. A Certificate of Good Health as required by the regulations of the Food and Drug Administration (F.D.A.) of the United States Department of Health and Human Services and Hillsborough County Ordinance 80-12.

C. An Affidavit, signed by the applicant and notarized, stating that said applicant has not been detained or treated for acute or chronic alcoholism during the preceding twelve months.

Section 3 — Fees

As required by Hillsborough County Ordinance 80-12

A. The fee for issuance of the Commercial Blood Plasma Vendor Identification Card shall be two dollars ($2.00) to be paid by the applicant.

B. The fee for issuance of a duplicate Commercial Blood Plasma Vendor Identification Card, under the provisions of Section 5(B) of Hillsborough County Ordinance 80-12, shall be two dollars ($2.00), to be paid to the applicant.

C. The fee for administration and maintenance of the Commercial Blood Plasma Vendor Identification system under the provisions of Hillsborough County Ordinance 80-12, shall be the sum of one dollar ($1.00), for each plasmapheresis procedure performed, to be paid by the plasmapheresis facility.

Section 4 — Breath Analysis

Alcohol level testing as required by Section 7 of Hillsborough County Ordinance 80-12, shall be performed by a qualified operator using a model 900 Smith and Wesson breath analyzer or equipment of equal quality.

Section 5 — Inspections

Pursuant to Section 10 of Hillsborough County Ordinance 80-12, duly authorized representatives of the Director of Hillsborough County Health Department will inspect each plasmapheresis facility within Hillsborough County not less than once annually. These inspections will be made without prior notice to the plasmapheresis facility. Such inspection shall include records required to be kept by the plasmapheresis facility under Hillsborough County Ordinance 80-12.

Section 6 — Additional Tests

In the event it is deemed necessary by a physician in the interests of the public health, the Hillsborough County Health Department may require specific tests in addition to those reported and/or an independent physical examination by a physician other than the physician issuing the applicant's Certificate of Good Health.

The Hillsborough County Health Department may delay issue of the Commercial Blood Plasma Vendor Identification Card for a period of ten (10) days if deemed necessary for examination testing, or investigative purposes.

Section 7 — Phase-In Period

As of the effective date of Hillsborough County Ordinance 80-12, no plasmapheresis facility within Hillsborough County may perform the plasmapheresis process on a commercial blood plasma vendor until said vendor presents the plasmapheresis facility with a valid Commercial Blood Plasma Vendor Identification Card; provided however, during the period of ninety

(90) days from the date these Rules and Regulations are adopted, each plasmapheresis facility may, nevertheless, perform the plasmapheresis procedure on a non card holder in instance where such commercial blood plasma vendors are vendors who have previously and regularly undergone the plasmapheresis procedure at that particular facility and where such vendors appear on that facility record of current vendors as of the effective date of Hillsborough County Ordinance 80-12.

Section 8 — Falsification of Information

In the case of falsification by a commercial blood plasma vendor of any information required by Hillsborough County Ordinance 80-12, or these Rules and Regulations promulgated pursuant thereto, the Hillsborough County Health department may deny the issuance of or revoke any existing Commercial Blood Plasma Vendor Identification Card of the person falsifying any information.

CERTIFICATION

This is to certify that the foregoing Rules and Regulations were promulgated pursuant to Section 10 of Hillsborough County Ordinance 80-12.

DONALD S. KWALECK, M.D.
Director of Hillsborough
County Health Department

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA

CASE NO. 81-1161-CIV-T-WC

AUTOMATED MEDICAL LABORATORIES, INC.,
Plaintiff,

-vs-

HILLSBOROUGH COUNTY, FLORIDA and
HILLSBOROUGH COUNTY HEALTH DEPARTMENT,
Defendants.

FILED March 18, 1982
Tampa, Fla.

ANSWER

COME NOW the Defendants, HILLSBOROUGH COUNTY, FLORIDA and the HILLSBOROUGH COUNTY HEALTH DEPARTMENT, by and through their undersigned attorneys, and file this their Answer to the Complaint filed by Plaintiff, AUTOMATED MEDICAL LABORATORIES, INC., and state that:

1. Admitted.

2. Without knowledge.

3. Admitted.

4. Admitted.

5. Denied.

6. Without knowledge.

7. Without knowledge.

8. Admitted.

9. Without knowledge.

10. Without knowledge.

11. Admitted.

12. Admitted.

13. Without knowledge.

14. Admitted.

15. Admitted.

16. Admitted.

COUNT I

17. Defendants reallege their answers to paragraphs 1 through 16 as stated above.

18. Without knowledge.

19. Denied.

20. Denied.

COUNT II

21. Defendants reallege their answers to paragraphs 1 through 20 as stated above.

22. Defendants deny that the requirements of Ordinances 80-11 and 80-12 and the regulations thereunder are burdensome, inconsistent or potentially inconsistent and Defendants are without knowledge of the remainder of the allegations contained in paragraph 22.

23. Denied.

24. Denied.

25. Denied.

COUNT III

26. Defendants reallege their answers to paragraphs 1 through 25 as stated above.

27. Without knowledge.

28. Denied.

29. Without knowledge.

30. Denied.

COUNT IV

31. Defendants reallege their answers to paragraphs 1 through 30 as stated above.

32. Defendants admit that Ordinances 80-11 and 80-12 and the regulations thereunder apply only to establishments which perform plasmapheresis on paid donors, but Defendants deny the remainder of the allegations contained in paragraph 32.

33. Denied.

COUNT V

34. Defendants reallege their answers to paragraphs 1 through 33 as stated above.

35. Defendants deny that Ordinance 80-11 requires "unspecified" information, but admit the remainder of the allegations contained in paragraph 35.

36. Denied.

37. Denied.

COUNT VI

38. Defendants reallege their answers to paragraphs 1 through 37 as stated above.

39. Denied.

40. Denied.

COUNT VII

41. Defendants reallege their answers to paragraphs 1 through 40 as stated above.

42. Admitted.

43. Denied.

44. Denied.

COUNT VIII

45. Defendants reallege their answers to paragraphs 1 through 44 as stated above.

46. Denied.

47. Denied.

COUNT VIII

48. Defendants reallege their answers to paragraphs 1 through 47 as stated above.

49. Admitted.

50. Denied.

COUNT X

51. Defendants reallege their answers to paragraphs 1 through 50 as stated above.

52. Admitted.

53. Denied.

COUNT XI

54. Defendants reallege their answers to paragraphs 1 through 53 as stated above.

55. Denied.

56. Denied.

COUNT XII

57. Defendants reallege their answers to paragraphs 1 through 56 as stated above.

58. Denied.

WHEREFORE, Defendants having fully answered the allegations contained in the Complaint respectfully pray that this Honorable Court dismiss this cause of action.

Respectfully submitted,

JOE HORN MOUNT and
DOLORES D. MENENDEZ
Attorneys for Defendant
Hillsborough County
P.O. Box 1110
Hillsborough County Courthouse
Tampa, Florida 33601

JANICE SORTOR
Attorney for Defendant Hillsborough
County Health Department
4000 W. Buffalo Avenue Room 520
Tampa, Florida 33614

[Certificate of Service omitted in printing.]

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

Case No. 81-1161-Civ-T-WC

AUTOMATED MEDICAL LABORATORIES, INC.,
Plaintiffs,
vs.
HILLSBOROUGH COUNTY, FLORIDA, et al.,
Defendants.

FILED CLERK, U.S. DISTRICT COURT
NOV. 1, 1982
MIDDLE DISTRICT OF FLORIDA, TAMPA, FLORIDA

OPINION

This cause came on before the Court on a non-jury trial on September 16 and 17, 1982. Plaintiff Automated Medical Laboratories, Inc. filed this action against Hillsborough County, Florida and the Hillsborough County Health Department, challenging the constitutionality of Hillsborough County Ordinances 80-11 and 80-12 and the Rules and Regulations promulgated thereunder. The challenged ordinances regulate licensing and operation of paid blood plasma donor centers. Plaintiff sought a declaratory judgment that the ordinances were unlawful and a permanent injunction against enforcement of the legislation.

Plaintiff challenged the ordinances on several grounds. It claimed that federal legislation preempted the local laws, that the local ordinances impermissibly burdened interstate commerce, and that the county ordinances unlawfully deprived Plaintiff of equal protection of the law by regulating only plasma centers that pay donors and not centers where unpaid volunteers donate whole blood. Plaintiff raised several other issues in the pleadings, such as unlawful delegation, violation of rights, privileges and immunities, and violation of due process. Plaintiff did not specifically adduce evidence or address these issues at trial, however, and the Court finds these arguments without merit.

Based on the evidence presented at trial and a review of the exhibits, the Court makes the following findings:

(1) Plaintiff is a Florida corporation that operates, through subsidiary corporations, eight blood plasma centers in the United States, one of which, Tampa Plasma Corporation, is located in Tampa, Hillsborough County, Florida. Plaintiff's plasma centers collect blood plasma from paid donors by plasmapheresis. In a single procedure this process removes whole blood from the donor, removes the plasma from the whole blood, and then returns the red blood cells to the donor. Plaintiff sells the plasma collected to pharmaceutical concerns that manufacture it as a raw material into products such as tetanus vaccine, albumin, and anti-hemophilic factor. Tampa Plasma Corporation collects and sells no whole blood.

(2) When Hillsborough County enacted the challenged ordinances, the Food and Drug Administration of the United States Department of Health and Human Services had issued regulations in 21 C.F.R. Subchapter F - Biologics that established standards and procedures for plasmapheresis operations. The regulations provide for FDA inspection of plasmapheresis facilities, establish standards for personnel and physical plants, necessitate licenses for plasmapheresis products and facilities, and establish human blood product standards, including the means to select suitable plasmapheresis donors.

(3) Hillsborough County Ordinance 80-11 imposes a license fee on plasmapheresis centers. The purpose of Hillsborough County Ordinance 80-12 is "to provide a system for the registration and identification of and the gathering of medical data applicable to Commercial Blood Plasma Vendors as being in the common interest of the health of the people of Hillsborough County." Pertinent provisions include the requirement that all plasma vendors obtain an identification card from the Health Department (at a cost of $2.00 as provided for in the rules and regulations pursuant to the ordinance). The ordinance requires the plasmapheresis centers to keep records of the procedures they perform, including the results of hepatitis testing, and to ascertain that a plasma vendor has not undergone a plasmapheresis procedure within specified time periods. The ordinance prohibits performance of the plasmapheresis procedure on any vendor who has not obtained a certificate of good health after examination by a physician. It imposes a fee, not to exceed

$1.00, for each procedure performed, with a limitation that fees collected shall not exceed the cost of administering and maintaining the identification system. It requires a pre-plasmapheresis breath analysis of each vendor by means of approved equipment, material, and supplies. The ordinance incorporates by reference the FDA regulations as they appear at 21 C.F.R., Subpart G, Section 640.60 et seq.

(4) In conformance with the FDA Regulations, Tampa Plasma Center currently provides its donors with identification cards. These cards are issued by individual centers, however, and plasma centers throughout the county do not cross-check with each other to ascertain whether a vendor has recently undergone plasmapheresis. The prospective vendor must give a medical history and undergo a physical examination, parts of which are performed by the center's non-medical personnel. A physician who has informed the vendor of the possible hazards and has questioned him about his understanding of the procedure accepts or rejects the vendor. After the plasmapheresis procedure is completed, a hepatitis test is performed and the plasma is kept in segregated storage until the center receives the results.

Under the county ordinances, the vendor would be required to obtain a county-wide identification card, which would not be issued prior to performance of a physical exam. The vendor would undergo a hepatitis test prior to registration, and breath analysis for alcohol content would be performed prior to each plasma donation.

(5) At trial, officers of the Plaintiff corporation attempted to establish the cost to Plaintiff of compliance with the ordinances. Their figures, however, were clouded with speculation. Mr. Dennis Healey, for instance, testified about a document he prepared (Exhibit 20) showing estimates of implementation costs. Except for the cost of the new fees, implemented by the Hillsborough County Health Department, the other estimated increased costs were based on Mr. Healey's opinion that the vendor population would decrease by twenty-five percent once the ordinances were enforced, primarily because the cost and inconvenience of obtaining the Health Department identification card would discourage new vendors. Mr. Healey, however, testified to no facts on which he based his opinion.

Plaintiff also encountered difficulty in estimating the increased cost per liter of plasma attributable to the requirement that the plasmapheresis center determine a prospective vendor's blood alcohol content by use of breathalyzer equipment manned by personnel with approved training. Plaintiff estimated that the machine alone would cost about $5,000.00; however, personnel training costs could not be estimated because approved training presently is available only through the Tampa Police Department.

(6) Much of the testimony at trial concerned the intent of the County Commissioners in enacting the ordinances. Plaintiff attempted to demonstrate that the ordinances were enacted in response to the social problems caused by inebriates and vagrants frequenting the area around the plasma centers. Plaintiff argued that the purpose of the regulations was to eliminate plasmapheresis centers from Hillsborough County by imposing severe economic burdens on their operations. Plaintiff failed to prove, however, that the legislative intent was anything other than that articulated in Ordinance 80-12 — to register and to identify vendors and to supplement and extend the federal regulations and their purposes.

(7) Defendants introduced testimony from physicians qualified as experts in the plasmapheresis field as to the need for and beneficial effect of a county-wide system of vendor identification. Under the federal regulations no system monitors the frequency with which individual vendors undergo the plasmapheresis procedure. Because of monetary inducements for undergoing plasmapheresis, vendors may donate plasma too frequently and put themselves in real danger of being overbled. This problem is particularly acute when the vendor is a chronic alcoholic with borderline liver function. The donor identification system will also help to insure the quality of the product in that vendors will be screened for hepatitis before they receive their identification cards, thus eliminating the hazards involved in handling potentially contaminated plasma.

Defendants' medical experts also expressed concern that a vendor under the influence of alcohol may not have sufficient understanding of the nature of the procedure and the risks it entails. The breathalyzer test requirement is intended to solve this problem. Under the federal regulations, however, Automated Laboratories, Inc. has established reliable procedures to screen

out persons under the influence of alcohol at two stages — when they are initially tested by the receptionist and when the physician examines them.

(8) The ordinances in question regulate only plasmapheresis centers that pay vendors. Testimony at trial showed that no whole blood centers in Hillsborough County pay donors. Furthermore, the legislators' concern for the safety of vendors and the quality of the product is applicable only to paid centers. Medical experts testified that plasma vendors have a much higher incidence of hepatitis than voluntary whole blood donors. Also, the problem of overbleeding does not exist among voluntary whole blood donors who have no monetary incentive to make frequent donations.

Based on the foregoing findings of fact the Court makes the following conclusions of law:

(1) Hillsborough County Ordinances 80-11 and 80-12 and the rules and regulations promulgated thereunder are not preempted by federal regulation. "There is neither such actual conflict between the two schemes of regulation that both cannot stand in the same area, nor evidence of a congressional design to preempt the field." *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 141 (1963). Plaintiff pointed to language in the Federal Register expressing the purpose of the federal regulations "to assure uniform adherence to the highest attainable standards of of [sic] practice in blood banking, including plasmapheresis and plasma fractionation," 39 Fed.Reg. 18614 (1974); but there is no evidence of express congressional intent to occupy the entire field of assuring high standards of practice in plasmapheresis. Moreover, the comprehensive nature of the federal legislation alone does not imply a congressional intent to preempt. *New York State Dep't. of Social Servs. v. Dublino*, 413 U.S. 405, 415 (1973). Finally, Hillsborough County Ordinances 80-11 and 80-12 supplement rather than conflict with the federal regulations, particularly in the ordinances' emphasis on ensuring vendor safety.

(2) Hillsborough County Ordinances 80-11 and 80-12 and the rules and regulations promulgated thereunder do not deprive Plaintiff of equal protection of the laws. Although the local legislation applies only to paid plasmapheresis centers and not to voluntary whole blood centers, Defendants successfully demon-

strated that there is a rational basis for regulating only the paid plasma centers. Because Plaintiff contends that the ordinances deprive Plaintiff of a property right rather than infringe upon a fundamental personal right, a rational basis for enactment of the statute is sufficient. *New Orleans v. Dukes*, 427 U.S. 297 (1976). This rational basis is evident from the following: vendors tend to sell their plasma more frequently than volunteers donate their whole blood; plasma vendors have a much higher rate of hepatitis than whole blood donors; and no paid whole blood centers exist in Hillsborough County.

(3) Hillsborough County Ordinance 80-11 and the rules and regulations promulgated thereunder do not place an impermissible burden on interstate commerce. Section 7 of Hillsborough County Ordinance 80-12 and Section 4 of the Rules and Regulations Pursuant to Hillsborough County Ordinance 80-12 impermissibly burden interstate commerce. The remainder of Hillsborough County Ordinance 80-12 and the Rules and Regulations Pursuant to Hillsborough County Ordinance 80-12 do not place an impermissible burden on interstate commerce.

The Supreme Court has stated the general rule for determining whether a state or local law is invalid by virtue of its effect on interstate commerce:

> Where the statute regulates evenhandedly to effect a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to putative public benefits. If a legitimate local purpose is found, then the question becomes one of degree. And the extent of the burden that will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities.

Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970).

For reasons previously stated, the Court finds that the ordinances regulate evenhandedly and serve a legitimate local purpose. The Court must therefore determine whether the burden, if any, imposed on interstate commerce is clearly excessive in relation to local benefits.

The Plaintiff was unable to demonstrate the total economic impact on it of enforcement of the ordinances. The evidence demonstrated, however, that significant protection for vendors would be assured by the vendor identification system, that the hepatitis pre-test requirement will help insure the quality of the product, and that the license and plasmapheresis fees will pay for the cost to the County of implementing and enforcing the ordinances. Clearly, all of these provisions, which will create some economic burden on the Plaintiff, will significantly benefit the health, safety, and welfare of the citizens of Hillsborough County.

The benefits of the breathalyzer requirement are not so readily apparent, however. Plaintiff demonstrated that the procedures it follows under the federal regulations achieved the same purpose as a breathalyzer test though the subjective evaluation of each potential vendor by the Plaintiff's personnel and physicians. Defendants did not demonstrate that the breathalyzer requirement, which will create a large, albeit precisely undedetermined [sic], economic burden on the Plaintiff, will "effectuate a legitimate public interest" that is not already achieved by Plaintiff's requirement with the federal regulations. Therefore, Section 7 of Hillsborough County Ordinance 80-12 and Section 4 of the Rules and Regulations Pursuant to Hillsborough County Ordinance 80-12 are invalid in that they impose an impermissible burden on interstate commerce.

Judgment will be entered in accordance with this Opinion.

DATED at Tampa, Florida this 1st day of November, 1982.

WILLIAM J. CASTAGNA
UNITED STATES DISTRICT JUDGE

Copies to:

Counsel of Record

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

Case No. 81-1161-Civ-T-WC

AUTOMATED MEDICAL LABORATORIES, INC.,
Plaintiffs,
vs.
HILLSBOROUGH COUNTY, FLORIDA, et al.,
Defendants.

FILED CLERK, U.S. DISTRICT COURT
NOV. 1, 1982
MIDDLE DISTRICT OF FLORIDA, TAMPA, FLORIDA

FINAL JUDGMENT

In accordance with the Opinion filed herein this date, it is

ADJUDGED:

Section 7 of Hillsborough County Ordinance 80-12 and Section 4 of the Rules and Regulations Pursuant to Hillsborough County Ordinance 80-12 are invalid in that they impose an impermissible burden on interstate commerce and the Defendants and their agents and employees are hereby enjoined from enforcing or attempting to enforce them.

As to the other claims of Plaintiff Automated Medical Laboratories, Inc., Judgment is entered in favor of the Defendants Hillsborough County, Florida and Hillsborough County Health Department, and Plaintiff shall take nothing.

DATED at Tampa, Florida this 1st day of November, 1982.

WILLIAM J. CASTAGNA
UNITED STATES DISTRICT JUDGE

Copies to:

Counsel of Record

AUTOMATED MEDICAL LABORATORIES, INC.,
Plaintiff-Appellant,
v.
HILLSBOROUGH COUNTY, Florida, and
Hillsborough County Health Department,
Defendants-Appellees.

No. 83-3014.

United States Court of Appeals,
Eleventh Circuit.

Jan. 16, 1984.

Appeal was taken from a judgment of the United States District Court for the Middle District of Florida, William J. Castagna, J., finding that parts of county ordinances regulating collection of blood plasma from paid donors by plasmapheresis were invalid. The Court of Appeals, Tuttle, Senior Circuit Judge, held that ordinances were implicitly preempted by federal regulation, as pervasiveness of federal regulatory scheme made it reasonable to infer that Congress left no room for local ordinances to supplement it, federal interest in plasmapheresis was dominant over any local interest, and enforcement of state law would present serious danger of conflict with administration of federal program.

Affirmed in part, reversed in part.

1. States 4.10
Preemption of state law by federal statute or regulation is not favored in the absence of persuasive reasons. U.S.C.A. Const. Art. 6, cl. 2.

2. States 4.10
Touchstone of a preemption analysis is congressional intent, which may be either express or implied. U.S.C.A. Const. Art, 6, cl. 2.

3. Counties 21½
Health and Environment 33
States 4.12

County ordinances regulating collection of blood plasma from paid donors by plasmapheresis were implicitly preempted by federal regulation, as pervasiveness of federal regulatory scheme made it reasonable to infer that Congress left no room for local ordinances to supplement it, federal interest in plasmapheresis was dominant over any local interest, and enforcement of state law would present serious danger of conflict with administration of federal program. U.S.C.A. Const. Art. 6, cl. 2; Public Health Service Act, §§ 2 et seq., 351, 42 U.S.C.A. §§ 201 et seq., 262; Federal Food, Drug, and Cosmetic Act, §§ 1 et seq., 201(g)(1), 21 U.S.C.A. §§ 301 et seq., 321(g)(1).

Larry A. Stumpf, Miami, Fla., for plaintiff-appellant.

Richard Landfield, Washington, D.C., for amicus Blood Resources Assoc. & FL Assoc. of Plasmapheresis Establishments.

Deolores D. Menendez and Emeline L. [sic] Acton, Tampa, Fla., for defendants-appellees.

Appeal from the United States District Court for the Middle District of Florida.

Before FAY and HENDERSON, Circuit Judges, and TUTTLE, Senior Circuit Judge.

TUTTLE, Senior Circuit Judge:

Appellant Automated Medical Laboratories, Inc. ("Automated") filed a civil action against appellees Hillsborough County, Florida (the "County") and Hillsborough County Health Department (the "Department") in the United States District Court for the Middle District of Florida. Appellant challenged the constitutionality of County Ordinances 80-11 and 80-12 ("County Ordinances") and the rules and regulations promulgated thereunder. Following a nonjury trial, United States District Court Judge William J. Castagna rejected all of Automated's constitutional attacks on the local legislation, including its federal preemption attack, except for the claim that § 7 of Ordinance 80-12 and § 4 of the rules and regulations imposed an impermissible burden on interstate commerce. This Court finds that the County Ordinances are pre-empted by federal regulation. Therefore,

the district court holding that § 7 of Ordinance 80-12 and § 4 of the rules and regulations are invalid is affirmed, and the holding that the remainder of the County Ordinances are valid is reversed.

I. BACKGROUND

Automated is a Florida corporation that operates, through subsidiary corporations, eight blood plasma centers in the United States. One of the centers, Tampa Plasma Corporation ("TPC"), is located in Tampa, Hillsborough County, Florida. Automated's plasma centers collect blood plasma from paid donors by plasmapheresis. Plasmapheresis is a process whereby, during a single procedure, blood is removed from a human donor, the plasma is removed from the whole blood, and the red blood cells are returned to the donor. Automated sells the plasma to pharmaceutical concerns, which use it in the manufacture of pharmaceutical products such as tetanus vaccine, albumin, and anti-hemophilic factor.

Prior to the enactment of the County Ordinances, the Food and Drug Administration of the United States Department of Health and Human Services ("FDA") had issued regulations, which are contained in 21 C.F.R. §§ 600.3-680.26 (1983) (the "federal regulations"), that established standards and procedures for plasmapheresis operations. The federal regulations provide for FDA inspection of plasmapheresis facilities, establish standards for personnel and physical plants, necessitate licenses for plasmapheresis products and facilities, and establish human blood product standards, including the means to select suitable plasmapheresis donors.

In conformance with the federal regulations, TPC selects plasma donors on the basis of medical history, tests, and physical examinations. On each potential donor's initial visit, and at four-month intervals thereafter, TPC's staff physician reviews the candidate's medical history, performs a physical examination, and decides whether to reject or accept the candidate. If the candidate is accepted, the physician explains the plasmapheresis procedure as well as its associated risks and obtains the candidate's written informed consent to having the plasmapheresis procedure performed. In addition to the regularly scheduled staff physician's review and examination, nonmedical employees of TPC, who are trained and supervised by

the staff physician, review the candidate's medical history prior to each donation of plasma. Nonmedical employees also determine, prior to each donation of plasma, that the candidate's weight, body temperature, blood pressure, pulse rate, serum protein, and hematocrit value are within the limits established by the federal regulations.

In conformance with the federal regulations, TPC has established procedures for eliminating from its donor population persons whose plasma could contain hepatitis virus. The staff physician rejects any candidate who has a history of viral hepatitis, a history of addiction to self-injected narcotics, or who has, within the preceding six months, had close contact with anyone having viral hepatitis, undergone major surgery, received whole blood or any human blood derivative known to be a possible source of viral hepatitis, or been tattooed. In addition, TPC sends a sample of each donation of plasma it collects to an outside laboratory operated by another wholly owned subsidiary of Automated to be tested for hepatitis contamination. If a sample is found to be contaminated, TPC destroys the unit of plasma from which the sample was taken and permanently rejects the donor from whom that unit was collected.

TPC has also established procedures for eliminating candidates who have exceeded the volume and frequency limits for plasma donations established in the federal regulations. To monitor the frequency with which a person donates plasma, TPC has established a donor identification system. At the time of a donor's first visit, TPC requires two forms of identification to establish the donor's identity. To identify the donor on subsequent visits, TPC provides the donor with an identification card, to which is affixed the donor's photograph. In addition, TPC establishes for each donor a permanent donor record file, which contains the donor's photograph and signature, as well as descriptive identifying information (address, telephone number, birthday, sex, height, eye and hair color, race, and blood type), written reports of the donor's physical examinations, signed consent forms, and written records documenting every plasma donation made. For each donation, TPC documents the date of donation, the bleed number, the donor's medical history and laboratory test results, and the volume of whole blood and red blood cells returned. By means of a permanent donor record file, TPC can deter any attempted donation which would result in a potential donor subjecting his or her health to risks by exceeding

the amount and frequency limits set forth in the federal regulations.

TPC is not required by the federal regulations to coordinate its donor identification system with that of other plasma centers in the County. If, however, circumstances warrant the checking of a potential donor's identity with another plasmapheresis center, TPC's phlebotomists examine both arms of the potential donor for signs of recent needle marks. Any potential donor who evidences recent needle marks that cannot be attributed to previous donations reflected in his or her permanent donor record file is referred to the staff physician for further evaluation.

The federal regulations provide for the inspection of TPC by an FDA official at least once every two years. The FDA inspection covers all aspects of the condition of TPC's facility, equipment, and records, as well as the methods used by TPC in collecting, processing, testing, storing, and shipping the plasma it collects. During the four years preceding the trial of this action, TPC was inspected approximately six times by the FDA. Those inspections apparently failed to reveal any deficiency in TPC's plasmapheresis operation other than a noisy fan or air conditioner in the staff physician's office, which allegedly made it difficult for one physician to communicate well with potential donors, forms that needed to be reprinted to make them clearly legible, and the observation, contested by TPC at the time of the inspection, that the staff physician had once "checked off" certain parts of a potential donor's physical examination form before actually performing them.

On November 26, 1980, the County adopted Ordinances 80-11 and 80-12. Ordinance 80-11 imposes a license tax and conditions the issuance of a license on, among other things, agreement by the blood plasma donor center to "reasonable and continuing access" by Department personnel for inspections, a public hearing, and continuously updated information regarding the owners, employees, equipment, and facilities.

The stated purpose of Ordinance 80-12 is "to provide a system for the registration and identification of and the gathering of medical data applicable to Commercial Blood Plasma Vendors as being in the common interest of the health of the people of Hillsborough County." On March 5, 1981, the Department issued rules and regulations pursuant to Ordinance 80-12.

Ordinance 80-12 requires that a potential donor must undergo a medical examination and obtain a "certificate of good health" before participating in the plasmapheresis process within the County. The regulations require that a potential donor present that certificate, together with his or her own sworn affidavit stating that he or she has not been detained or treated for acute or chronic alcoholism during the preceding twelve months, to the Department. The Department then issues its own identification card to the potential donor. This identification card permits the potential donor to undergo plasmapheresis for a period of six months only at a single specified plasmapheresis facility located within the County.

Ordinance 80-12 also requires that TPC submit to the Department on a daily basis information as to each plasmapheresis procedure performed, including the following: the date of the procedure; the name, address, age, weight, height, sex, identification number, and current hematocrit value of the donor; the results of the donor's breath analysis; the amount of whole blood removed and the proportion of red cells returned; and the results of testing for hepatitis. Neither the ordinance nor the regulations indicate what use the Department is to make of this information. Ordinance 80-12 and the regulations also require TPC to pay the Department a fee of $1.00 for each plasmapheresis procedure it performs. The purpose of this fee seems to be limited to maintaining the bureaucracy needed to store the information provided by TPC.

Ordinance 80-12 authorizes the Department to inspect TPC periodically, even though the Department apparently employs no qualified inspector. The regulations provide that such inspections shall occur at least annually. Finally, Ordinance 80-12 subjects TPC to criminal sanctions for violation of its provisions.

II. DISCUSSION

The first issue before this Court is whether County Ordinances 80-11 and 80-12 and the rules and regulations promulgated thereunder are pre-empted by the federal scheme.

[1,2] The rationale underlying the pre-emption doctrine is that the Supremacy Clause invalidates state laws that "interfere with or are contrary to, the laws of congress. . . ." *Gibbons v.*

Ogden, 9 Wheat. 1, 211, 6 L.Ed. 23 (1824). Pre-emption of state law by federal statute or regulation is not favored in the absence of persuasive reasons. *Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317, 101 S.Ct. 1124, 1130, 67 L.Ed.2d 258 (1981); *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142, 83 S.Ct. 1210, 1217, 10 L.Ed.2d 248 (1963). The touchstone of a pre-emption analysis is congressional intent, which may be either express or implied. *Fidelity Federal Savings & Loan Association v. De La Cuesta*, 458 U.S. 141, 151, 102 S.Ct. 3014, 3022, 73 L.Ed.2d 664, 675 (1982); *Jones v. Rath Packing Co.*, 430 U.S. 519, 529, 97 S.Ct. 1305, 1309, 51 L.Ed.2d 604 (1977); *Howard v. Uniroyal, Inc.*, 719 F.2d 1552 at 1555-56 (11th Cir. 1983). In *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. at 143, 83 S.Ct. at 1218, 10 L.Ed.2d 248, the Supreme Court stated a two-pronged analysis for pre-emption claims: "Does either the nature of the subject matter, ... or any explicit declaration of congressional design to displace state regulation, require [the challenged legislation] to yield to the federal [regulatory scheme]?" We must first examine the federal law for an explicit declaration of Congress's intent to pre-empt state law.

Blood and blood components are biological products subject to the Public Health Service Act, 42 U.S.C.A. § 262 (1982), and are drugs subject to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. § 321(g)(1) (1972). *See Blank v. United States*, 400 F.2d 302, 305-06 (5th Cir. 1968); *United States v. Calise*, 217 F.Supp. 705, 709 (S.D.N.Y. 1962). The Public Health Service Act establishes licensing and product standards and the Federal Food, Drug, and Cosmetic Act provides that unadulterated drugs may not be shipped in interstate commerce. Neither

statute expressly precludes state action[1]. Nor do the applicable regulations explicitly dictate pre-emption[2]. *See* 21 C.F.R. §§ 600.3-680.26 (1983).

[3] Having found no express intent to pre-empt state law, we next examine Congress's implicit intent in enacting the federal scheme. "Where Congress has not stated specifically whether a federal statute has occupied a field in which the states are otherwise free to legislate, different criteria have furnished touchstones for decision." *Pennsylvania v. Nelson*, 350 U.S. 497, 501-02, 76 S.Ct. 477, 479-80, 100 L.Ed. 640 (1956) (footnote omitted). *Accord Howard v. Uniroyal, Inc.*, 719 F.2d 1552 at 1556 (11th Cir. 1983). Three tests are set out in *Pennsylvania v. Nelson* to determine if state law is implicitly pre-empted.

The first test is whether the federal scheme is so pervasive as to make reasonable the inference that Congress left no room for the states to supplement it. *Pennsylvania v. Nelson*, 350 U.S. at

---

[1] The attorney for the American Blood Resources Association and the Florida Association of Plasmapheresis Establishment, parties who appeared as amici curiae, argue that section 351 of the Public Health Service Act explicitly expresses Congress's intent to pre-empt state law. Section 351 provides in relevant part:

> (a) No person shall sell, barter or exchange, ... or send, carry or bring for sale, barter or exchange ... any ... blood, blood component or derivative ... unless (1) such ... blood, blood component, or derivative ... has been propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license, issued by the Secretary as hereinafter authorized, ... (d) Licenses for the maintenance of establishments ... may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations .... All such licenses shall be issued, suspended, and revoked as prescribed by regulations....

42 U.S.C.A. § 262 (1982).

This Court does not find that the statute contains express language indicating pre-emption. *Cf., Armour and Company v. Ball*, 468 F.2d 76 (6th Cir. 1972), *cert. denied*, 411 U.S. 981, 93 S.Ct. 2267, 36 L.Ed.2d 957 (1973) (federal statute in question expressly provided that requirements in addition to, or different than, those made under the statute may not be imposed by any state).

[2] "Federal regulations have no less pre-emptive effect than federal statutes." *Fidelity Federal Savings & Loan Association v. De La Cuesta*, 458 U.S. 141, 151, 102 S.Ct. 3014, 3022, 73 L.Ed.2d 664 (1982) (Supreme Court found preemption where the preamble accompanying the regulations unequivocally expressed intent to pre-empt conflicting state law). *Accord, United States v. Jones*, 707 F.2d 1334, 1336-37 (11th Cir. 1983).

502, 76 S.Ct. at 480, 100 L.Ed. 640. The federal scheme set out in the statutes and implementing regulations at issue here is comprehensive. The three basic requirements of section 351 of the Public Health Service Act ("Act") are that each establishment producing a biological product be licensed, each product be licensed based on standards designed to insure safety, purity, and potency, and that the package and labeling meet specified standards. 42 U.S.C.A. § 262 (1982). Within the federal regulations implementing the Act, 21 C.F.R. §§ 600.3-26 (1983)[3], one part deals specifically with "Source Plasma (Human)," which is defined as the fluid portion of human blood collected by plasmapheresis and intended as source material for further manufacturing use. 21 C.F.R. §§ 640.60-640.76 (1983)[4]. Other portions of the regulations implementing the Act also apply to plasmapheresis[5].

The federal regulations are broad in scope and cover virtually every phase of the plasmapheresis process. The pervasiveness of the regulatory scheme makes it reasonable to infer that

[3] Pursuant to Section 361 of the Act, 42 U.S. C.A. § 264 (1982), and under authority delegated to him, 21 C.F.R. § 5.10, the Commissioner of Food and Drugs is authorized to promulgate regulations. When an administrator promulgates regulations intended to pre-empt state law, the court will not disturb his efforts unless he has exceeded his statutory authority or acted arbitrarily. In examining pre-emption regulations, the court must ask whether the administrator intended to pre-empt state law, and if so, whether that action is within the scope of the administrator's delegated authority. *Fidelity Federal Savings & Loan Association v. De La Cuesta*, 458 U.S. at 151, 102 S.Ct. at 3022, 73 L.Ed.2d 664. In this case, there is no contention that the regulations promulgated pursuant to the Act exceed statutory authority. It does not appear to the Court that the regulations extend beyond the authority granted by Congress.

[4] The regulations prescribe rules as to consent of a prospective donor, medical supervision of the procedure, suitability of donors, method of collection, requirements of the plasmapheresis procedure, immunization of donors, testing for hepatitis, processing of the blood, pooling, inspection, labeling, manufacturing responsibility, records, reporting of fatal donor reactions, modification of source plasma, alternate procedures, and products stored or shipped at unacceptable temperatures.

[5] The subjects included within the remaining regulations are establishment standards and inspection, 21 C.F.R. §§ 600.3-22 (1983); licensing, 21 C.F.R. §§ 601.1-601.33 (1983); good manufacturing practices for blood and blood components, 21 C.F.R. §§ 606.3-606.170 (1983) (with specific sections relating to personnel, facilities, equipment, supplies and reagents, standard operating procedures, finished product and laboratory controls, labeling, records, and reports); establishment registration and product listing, 21 C.F.R. §§ 607.3-607.65 (1983); general biological products standards, 21 C.F.R. §§ 610.65 (1983) (including standards of potency, hepatitis requirements, dating periods, and labeling standards).

Congress left no roon *sic* for local ordinances to supplement it. *See Howard v. Uniroyal, Inc.*, 719 F.2d 1552 at 1559 (11th Cir. 1983). Nevertheless, pre-emption is not to be inferred merely from the comprehensiveness of the federal scheme. *New York State Department of Social Services v. Dublino*, 413 U.S. 405, 415, 93 S.Ct. 2507, 2514 37 L.Ed.2d 688 (1973).

The second test under *Pennsylvania v. Nelson* is whether the federal statute touches a field in which the federal interest is so dominant that the federal system must be assumed to preclude enforcement of state laws on the same subject. *Pennsylvania v. Nelson*, 350 U.S. at 504, 76 S.Ct. at 481, 100 L.Ed. 640. Congress has maintained extensive and comprehensive control over the nation's blood collection since 1946. 38 Fed.Reg. 2966 (1973). The collection of blood is an area of national concern, for "[h]uman blood is a priceless resource." 39 Fed.Reg. 18614 (1974). According to the Commissioner of Food and Drugs:

> The promulgation of standards for these biological drugs is part of an existing effort to increase the quality of blood related health care in this country. Pursuant to the findings of a special Task Force in Blood Banking, the Secretary of Health, Education, and Welfare has established a *comprehensive National Blood Policy*. One of the fundamental methods prescribed by the Secretary to implement the policy is to "employ the full regulatory authorities now vested in the Federal Government ... for the purpose of assuring uniform adherence to the highest attainable standards of practice in blood banking, including plasmapheresis and plasma fractionation."

39 Fed.Reg. 18614 (1974) (emphasis added). *See also* 39 Fed.Reg. 18615 (1974) ("Such regulations are within the broad Congressional mandate to pursue the high remedial public health purpose of both the Federal Food, Drug and Cosmetic Act and the Public Health Service Act.") Furthermore, the Supreme Court has indicated that the Food, Drug, and Cosmetic Act should be given a liberal construction consistent with its overriding purpose to protect the public health. *See United States v. An Article of Drug ... Bacto-Unidisk ...*, 394 U.S. 784, 798, 89 S.Ct. 1410, 1418, 22 L.Ed.2d 726 (1960); *United States v. Dotterweich*, 320 U.S. 277, 280, 64 S.Ct. 134, 136, 88 L.Ed. 48 (1943).

Although the County possesses an interest in the health of

its residents, federal laws may still preclude enforcement of the County scheme. *See Fidelity Federal Savings & Loan Association v. De La Cuesta*, 458 U.S. 141, 151, 102 S.Ct. 3014, 3022, 73 L.Ed.2d 664 (1982) (pre-emption is not inapplicable simply because real property is a matter of special concern to the states). The regulations clearly express a federal interest in establishing a uniform "National Blood Policy." *Cf. Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 143-44, 83 S.Ct. 1210, 1218, 10 L.Ed.2d 248 (1963) (the maturity of avocados is an inherently unlikely candidate for exclusive federal regulation). Therefore, we conclude that the federal interest in plasmapheresis is dominant over any local interest.

The third test in *Pennsylvania v. Nelson* is whether the enforcement of state law presents a serious danger of conflict with the administration of the federal program. 350 U.S. at 505, 76 S.Ct. at 482, 100 L.Ed. 640. The Commissioner of Food and Drugs described the purpose of the federal scheme as follows:

> To insure there is a continued healthy donor population to serve as a source of plasma to be used in the manufacture, by the fractionation technique, of safe, pure, and potent blood products, the Commissioner is including in these proposed additional standards for Source Plasma (Human) specific provisions designed to protect the health and well-being of the donor.

37 Fed.Reg. 17420 (1972). Thus, the regulations were designed to protect the plasma donors, to insure that the product is safe, and to insure the continued existence of a healthy donor population. *See also* 39 Fed.Reg. 26162 (1974); 39 Fed.Reg. 18615 (1974); 41 Fed.Reg. 10762-63 (1976). The regulations were also enacted to establish uniform standards for blood banking. 39 Fed.Reg. 26161 (1974). The goal of uniformity runs throughout the regulations. *See, e.g.*, 48 Fed.Reg. 26313 (1983) (one reason for regulations establishing FDA inspection at least once every two years is to provide uniformity in the frequency of inspection).

The purpose of the County scheme is similar to that of the federal scheme. Section 15 of Ordinance 80-12 incorporates by reference the federal regulations appearing at 21 C.F.R. Part 640, Subpart G, Section 640.60 *et seq*. As noted earlier, these are the provisions of the federal regulatory scheme relating solely to

"Source Plasma (Human)." The other provisions of the County Ordinances, however, impose additional requirements on plasmapheresis centers.[6]

These additional County requirements cover areas that are clearly encompassed by the federal regulations. Unlike *Smith v. Pingree*, 651 F.2d 1021, 1025 (5th Cir. 1981) (Unit B), in which the court found that the federal requirements did not regulate every aspect of the area and so the state had the implied reservation to fill out the scheme, the federal scheme here regulates every aspect of plasmapheresis. The County scheme imposes burdensome and expensive requirements in addition to the requirements of the comprehensive federal scheme. If the County scheme remains in effect, the national blood policy of promoting uniformity and guaranteeing a continued supply of healthy donors will be adversely affected. *See Campbell v. Hussey*, 368 U.S. 297, 301, 82 S.Ct. 327, 329, 7 L.Ed.2d 299 (1961) (pre-emption found where act refers to need for uniform official standards); *Howard v. Uniroyal*, 719 F.2d 1552 at 1560 (11th Cir. 1983) (pre-emption found where one of Congress's objectives was to insure that there would be a uniform, consistent federal approach).

Thus, Automated has satisfied the three tests set out in *Pennsylvania v. Nelson*. This Court holds that Hillsborough County Ordinances 80-11 and 80-12 and the implementing rules and regulations are pre-empted by the federal scheme. The Court need not reach any other issues raised on appeal. Accordingly, the judgment of the district court finding Section 7 of Ordinance 80-12 and § 4 of the rules and regulations invalid is AFFIRMED, the judgment finding the remaining sections of the County Ordinances and implementing rules and regulations valid is REVERSED.

---

[6] The County scheme adds the following requirements: 1) A person may donate plasma only after obtaining a donor registration card, at a cost of $2.00, valid for six months at a single designated plasma center; 2) a donor registration card is issued only after the donor receives a complete physical exam and a hepatitis test and presents a sworn statement that within the preceding year, he or she has not been treated for chronic or acute alcoholism; 3) the plasma center must keep and forward daily to the Department records of the donors and procedures performed; 4) each donor must undergo a breath analysis prior to donation; 5) the Department shall inspect the plasma center at least once a year, and 6) the plasma center must pay the Department $1.00 for each plasmapheresis procedure performed.

United States Court of Appeals
FOR THE ELEVENTH CIRCUIT

NO. 83-3014

D.C. Docket No. 81-1161[sic]-WC

AUTOMATED MEDICAL LABORATORIES, INC.,
Plaintiff-Appellant,

versus

HILLSBOROUGH COUNTY, FLORIDA, and
HILLSBOROUGH COUNTY HEALTH DEPARTMENT,
Defendants-Appellees.

Appeal from the United States District Court for the
Middle District of Florida

Before FAY and HENDERSON, Circuit Judges, and TUTTLE, Senior Circuit Judge.

J U D G M E N T

This cause came on to be heard on the transcript of the record from the United States District Court for the Middle District of Florida, and was argued by counsel;

ON CONSIDERATION WHEREOF, it is now here ordered and holding adjudged by this Court that the judgment of the District Court finding Section 7 of Ordinance 80-12 and § 4 of the rules and regulations invalid is AFFIRMED; the judgment finding the remaining sections of County Ordinances 80-11 and 80-12 and implementing rules and regulations valid is REVERSED;

It is further ordered that defendants-appellees pay to plaintiff-appellant, the costs on appeal to be taxed by the Clerk of this Court.

ISSUED AS MANDATE: MAR 8- 1984

Entered: January 16, 1984
For the Court: Spencer D. Mercer, Clerk
BY: _____
Deputy Clerk

(5)

No. 83-1925

IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

HILLSBOROUGH COUNTY, FLORIDA, *et al.*,
Appellants

v.

AUTOMATED MEDICAL LABORATORIES, INC.

On Appeal from the United States Court of Appeals for the Eleventh Circuit

---

BRIEF OF THE NATIONAL ASSOCIATION OF COUNTIES, INTERNATIONAL CITY MANAGEMENT ASSOCIATION, NATIONAL CONFERENCE OF STATE LEGISLATURES, NATIONAL LEAGUE OF CITIES AND U.S. CONFERENCE OF MAYORS AS *AMICI CURIE* IN SUPPORT OF APPELLANTS

BENJAMIN W. HEINEMAN, JR.
CARTER G. PHILLIPS
SIDLEY & AUSTIN
1722 Eye Street, N.W.
Washington, D.C. 20006
(202) 429-4000

JOYCE HOLMES BENJAMIN *
STATE AND LOCAL LEGAL CENTER
444 N. Capitol Street, N.W.
Suite 349
Washington, D.C. 20001
(202) 638-1445

Counsel for the Amici Curiae

* Counsel of Record

35pp

QUESTION PRESENTED

Whether regulations of the Food and Drug Administration ("FDA"), which set minimum federal standards for the collection and transportation of blood and blood products, including blood plasma, preempt Hillsborough County's Ordinances #80-11 and #80-12, which provide additional but not conflicting safety standards for the collection of blood plasma from paid donors.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES:

TABLE OF AUTHORITIES—Continued

STATUTES AND REGULATIONS:

TABLE OF AUTHORITIES—Continued

IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

No. 83-1925

HILLSBOROUGH COUNTY, FLORIDA, *et al.*,
Appellants

v.

AUTOMATED MEDICAL LABORATORIES, INC.

On Appeal from the United States Court of Appeals for the Eleventh Circuit

BRIEF OF THE NATIONAL ASSOCIATION OF COUNTIES, INTERNATIONAL CITY MANAGEMENT ASSOCIATION, NATIONAL CONFERENCE OF STATE LEGISLATURES, NATIONAL LEAGUE OF CITIES AND U.S. CONFERENCE OF MAYORS AS *AMICI CURIE* IN SUPPORT OF APPELLANTS

INTEREST OF *AMICI CURIAE*

Amici are organizations whose members include state, county and municipal governments and officials located throughout the United States. *Amici* and their members therefore have a vital interest in the legal issues that affect the powers and responsibilities of state and local government.

The court of appeals held that FDA regulations concerning blood plasma centers preempt two ordinances enacted by Hillsborough County, even though the federal regulations were not expressly intended to preempt local law and do not conflict with any provisions of the County ordinances. This holding involves a dramatic extension of the preemption doctrine because it sanctions *implied*

preemptions by federal agencies, not the Congress, when no conflict between federal and local law has been established. The holding thus significantly infringes on the ability of state and local governmental units to undertake concurrent and supplemental regulation on matters affecting public health and safety, an area traditionally regulated by the state's police power. *See Head v. New Mexico Board of Examiners*, 374 U.S. 424, 428 (1963); *Barsky v. Board of Regents*, 347 U.S. 442, 449 (1954). Unless this Court holds that, absent preemptive intent by the Congress, federal regulatory agencies must either expressly state their intention to preempt or must clearly demonstrate a conflict between federal and local law, this case will have a direct, immediate and adverse effect on matters of vital importance to *amici* and their members. *Amici* are therefore submitting this brief to assist the Court in its resolution of this action.[1]

STATEMENT

(1) The Public Health Service Act and the FDA's Regulations

In 1970, Congress amended Section 347 of the Public Health Service Act, 42 U.S.C. § 262, to include, *inter alia*, blood and blood "products" (blood components or derivatives) within the licensing authority of the (now) Department of Health and Human Services ("HHS") and its subordinate agency, the Food and Drug Administration ("FDA"). Pub. L. 85-881, § 2, 72 Stat. 1074.[2]

[1] Pursuant to Rule 36 of the Rules of this Court, the parties have consented to the filing of this brief. The parties' letters of consent have been filed with the Clerk of the Court.

[2] FDA implements Section 347 under delegated authority from the Secretary of HHS. 42 U.S.C. § 264. The FDA licensed blood preparation facilities prior to 1970, but the Fifth Circuit declared the FDA's regulation of blood banks to be beyond the agency's statutory authority. *Blank v. United States*, 400 F.2d 302 (5th Cir. 1963). Congress then amended the statute to make it clear that the FDA's licensing authority extended to blood and blood products. H.R. Rep. No. 91-1035, 91st Cong., 2d Sess. 1-3 (1970); *Communicable Disease and Immunization Programs*, Hearings before the Subcommittee on Public Health and Welfare of the House Committee on Interstate and Foreign Commerce, 91st Cong., 2d Sess. 10-11 (1970) (remarks of Dr. Robert Marston, Director National Institute of Health).

Section 347, the single provision governing this licensing scheme, requires blood or blood components that are transported in interstate commerce to be prepared at an establishment holding a valid FDA license. 42 U.S.C. § 262(a). The licenses are to be issued upon a showing of compliance with FDA standards "designed to insure the continued safety, purity, and potency of such products. . . ." 42 U.S.C. § 262(d). FDA is authorized in its discretion to inspect such establishments for compliance with the regulatory standards. 42 U.S.C. § 262(c) and (d). The statute contains no specific requirements for receipt of a license and contains no provision concerning the relationship between this provision and state law.

The FDA has adopted regulations implementing the 1970 amendment which govern various types of blood products and blood banking activities. 21 C.F.R. 600, 601, 606, 610 and 640.[3] Standards for blood plasmapheresis —the process of removing plasma from whole blood—are set out in Subpart G of Part 640. Like the statute, these regulations are intended to ensure the quality of the blood products derived from plasma, but the regulations also set minimum standards in order to protect donors from practices that might endanger their health. *See* 39 Fed. Reg. 26161 (1974). Specifically, the regulations require that the facility obtain the donor's written informed consent (21 C.F.R. 640.61); require that a licensed physician be present and that either he or someone under his supervision, determine the donor's suitability for the proce-

[3] There are special regulations concerning plasmapheresis because donors ordinarily receive compensation for undergoing the procedure, which creates unique public health problems. *See* 39 Fed. Reg. 26161 (1974).

dure (21 C.F.R. 640.63); and, finally, require that an examining physician issue a certificate that the donor is in good health (21 C.F.R. 640.63). The regulations also prescribe a set of donor qualifications, which include normal temperature, normal pulse rate and freedom from a history of or recent contacts with hepatitis. 21 C.F.R. 640.63(c). Finally, any person who appears intoxicated or otherwise unable or unwilling to answer questions truthfully should be considered unsuitable for plasmapheresis. 21 C.F.R. 640.63(d).[4] To monitor these standards, FDA requires records to be kept on each donor. 21 C.F.R. 640.72. Nothing in the regulations or in the original statement of reasons for adopting the regulations indicates that the FDA's regulations were intended to be the maximum or exclusive requirements for plasmapheresis licensees or were otherwise intended to preempt state authority to adopt supplemental or complementary safety standards for such facilities.

(2) Hillsborough County's Ordinances

In November 1980, Hillsborough County, Florida ("County") enacted Ordinances #80-11 and #80-12,[5] which, combined with the implementing regulations adopted by the County's Health Department in March 1981,[6] broadly regulate the practices of commercial blood plasma facilities. (J.S. App. A5). Ordinance #80-11 is a licensing statute, which requires every blood plasma[7]

[4] The regulations also establish minimum standards for conducting plasmapheresis, and for processing, storing and labelling plasma units obtained during the procedure. 21 C.F.R. 640.65, 640.68 and 640.70.

[5] Both ordinances are reproduced in full at J.S. App. A29-A39.

[6] The Health Department's regulations implementing County Ordinance #80-12 are reproduced in full at J.S. App. A40-A42.

[7] Blood plasma donors are individuals who sell "the liquid portion of his or her blood (plasma), through the plasmapheresis process." (Ord. 80-12, § 3(A); J.S. App. A33). "Plasmapheresis" was defined by the district court in its findings of fact as follows: "In a single procedure this process removes whole blood from the donor,

center to pay a license tax and permits the Health Department access to the centers to inspect for violations of the County's health standards. (J.S. App. A29-A30).

Ordinance #80-12 establishes "a system for the registration . . . and the gathering of medical data applicable to" donors who give blood at centers and receive compensation. (Ordinance 80-12, § 2; J.S. App. A32). Specifically, Ordinance #80-12 creates a donor identification system requiring each person who wishes to sell plasma to obtain a donor identification card which is valid at only *one* plasmapheresis facility within the County. (Ordinance 80-12, §§ 4-5; J.S. App. A33). Each facility in the County is prohibited from performing the plasmapheresis procedure on any individual who has not presented a valid identification card for that facility. For each procedure, the facility must also fill out a form, which contains basic information about the donor and the quantity and quality of plasma sold to the facility. This information is then delivered to the County Health Department on a daily basis. (Ordinance 80-12, § 6(A), (B); J.S. App. A33-A34).

Ordinance #80-12 also requires each facility to ascertain the basic fitness of each donor to undertake the plasmapheresis procedure. The facility must determine how much blood the donor has had removed recently, make sure the donor has a certificate of good health from a physician who has personally examined him and analyze the breath of the donor with a breathalyzer to assure that his or her blood alcohol content does not exceed .07 per cent. (Ord. #80-12, §§ 6-7; J.S. App. A35-A36). Finally, the Ordinance incorporates by reference Part 640 of Title 21 of the Code of Federal Regulations—the

removes the plasma from the whole blood, and then returns the red blood cells to the donor." (J.S. App. A14). *See id.* at A3, A33). Although the ordinances refer to individuals who sell their blood to plasmapheresis centers as "vendors," we will refer to such individuals as "donors," to avoid confusion with the centers, which also sell blood plasma.

FDA's regulations "concerning plasmapheresis and source plasma (human)." (Ord. 80-12, § 15; J.S. App. A39).[6]

Ordinance #80-12 explains that the identification system was adopted because the Board of County Commissioners found "that the interests of the public health mandate the monitoring of the plasmapheresis procedure within Hillsborough County." (J.S. App. A32). In addition, the express purpose of the Ordinance "is to provide a system for the registration and identification of and the gathering of medical data applicable to Commercial Blood Plasma [donors] as being in the common interest of the health of the people of [the County]." (Ord. 80-12, § 2; J.S. App. A32-A33). At trial, County officials testified that the major purposes of the County's scheme are to prevent donors from the risk of overbleeding by going from one center to another (Tr. 151-152) and to make certain that donors are not so intoxicated that they cannot give an informed consent to the procedure (Tr. 149-151). Finally, the County wanted generally to prevent chronic alcoholics and individuals with hepatitis from undergoing the plasmapheresis procedure; the former because the process poses a serious health risk to the donor (Tr. 189) and the latter because the contaminated blood poses a serious health risk to employees of the plasmapheresis centers (Tr. 149).

Certain obligations imposed by the County are not contained in the FDA's regulations: (a) the County requires the centers to fill out an additional form for each procedure; (b) the County requires the donors to pay an initial fee and the centers to pay both a license tax and additional fees to cover the County's administrative ex-

[6] To cover its expenses in processing the various forms required under the scheme created by the two ordinances, the County charges a ten dollar fee for a donor identification card and a one dollar fee for each plasmapheresis procedure performed by a facility. (Ord. 80-12, §§ 5(A), 6(F); J.S. App. A33, A35).

penses; (c) the County also requires each vendor to have a center-specific identification card so that he cannot sell blood to more than one center within the County; (d) the County requires a breathalyzer test to be administered and passed before the plasmapheresis procedure can be performed; and (e) the County has its own system of inspecting the centers to ensure compliance with both the County's particular regulations and those of the FDA that have been incorporated by reference.

(3) Proceedings in the Lower Courts

Appellee, a Florida corporation which wholly owns a plasmapheresis center in Hillsborough County, filed suit in the United States District Court for the Middle District of Florida, challenging various provisions in the County's Ordinances #80-11 and #80-12, as unconstitutional under a variety of legal theories. After a bench trial, the district court upheld most of the provisions of the ordinances against all constitutional attacks (J.S. App. A13-A19), but did declare the breathalyzer requirement to be invalid as "an impermissible burden on interstate commerce" (*id.* at A19).

In upholding the rest of the provisions in the ordinances, the district court found that there was a "need for and beneficial effect of a county-wide system" of donor identification, because federal regulations contain no system to monitor "the frequency with which individual [donors] undergo the plasmapheresis procedures" (*id.* at A16). The court further found that because people are paid for selling plasma, they are relatively likely to "put themselves in real danger of being overbled" by donating too frequently at different centers. (*ibid*). Finally, the court found that "significant protection for [donors] would be assured" by the donor identification system and that "the license and plasmapheresis fees will pay for the cost of the County of implementing and enforcing the ordinances" (*id.* at A18).

The district court held that the ordinances were not preempted by federal law because there was (1) no evidence of express Congressional intent to preempt state law, (2) an insufficient indication of any implicit Congressional intent to occupy the field of blood plasma regulation and (3) no specific conflict between the ordinances' requirements and those contained in the FDA's regulations (*id.* at A17).

On cross-appeals, the court of appeals affirmed in part and reversed in part (J.S. App. A1-A12). The court of appeals held that all of the provisions in the ordinances, including the breathalyzer provision, were preempted by federal law. Like the district court, the court of appeals concluded that Congress had not expressly preempted state or local law and that the applicable regulations did not explicitly preempt local regulations (*id.* at A7). In addition, the court of appeals cited no facts of record showing that there was any specific conflict between the FDA's regulations and the ordinances. Nevertheless, applying the tests of *Pennsylvania v. Nelson*, 350 U.S. 497 (1956), the court of appeals concluded that the FDA's regulations by their scope and emphasis on uniformity implicitly occupied the field of plasmapheresis regulation and therefore even complementary local law requirements for safeguarding the health of plasma donors and center employees could not survive. The court also held that the County's ordinances would interfere with the FDA's regulatory purpose of assuring a continuing supply of healthy donors. The County then filed a jurisdictional statement and this Court noted probable jurisdiction.

---

[9] The court of appeals did not declare "clearly erroneous" the district court's findings that there was no conflict between the federal and County requirements (Fed.R.Civ. P. 52(a)), and did not consider the Commerce Clause issues.

SUMMARY OF ARGUMENT

At stake in this case is the ability of state and local governments to exercise their traditional police powers to supplement minimum requirements of federal agencies by adopting non-conflicting health and safety standards that respond to local needs. This is not a case where a local government seeks to oust federal authority by adopting laws that conflict with federal law. Instead, Hillsborough County has created a local system of regulation that embraces the federal government's requirements and merely adds to them to achieve health and safety objectives that complement, and do not conflict with, the purposes of the federal regulatory regime.

(1) In *Fidelity Federal Savings & Loan Ass'n. v. De La Cuesta*, 458 U.S. 141 (1982) and *Capital Cities Cable, Inc. v. Crisp*, —— U.S. ——, 104 S.Ct. 2694 (1984), this Court required that preemptive intent of a *federal regulatory agency* be clearly established before the agency could nullify *non-conflicting* state law. Accordingly, the court of appeals erred in holding that a federal administrative agency can preempt even complementary state and local public health standards without the agency stating expressly in its regulations its intent to occupy the field of regulation.

Comity between federal and state interests requires rejection of the ruling by the court of appeals that preemption of non-conflicting state law can be implied from agency regulations alone. Under *De La Cuesta*, federal agencies have extraordinary power to oust non-conflicting state regulation whenever they do so expressly in their regulations pursuant to valid delegated authority and with an adequate statement of reasons. Requiring federal agencies to act expressly when they intend to use their preemption power over non-conflicting state law is the least that should be required under sound principles of federalism. For this Court to allow federal agencies

to preempt a field, absent express or implied congressional intent and without an express statement of agency intent, denies state and local officials a reasonable opportunity to comment and to engage the agency in a dialogue concerning whether preemption of non-conflicting state law is in the public interest. Such a holding will also create needless uncertainty for state and local agencies concerning the scope of what they can regulate, and permit private interests to challenge in federal court virtually any local attempt to supplement existing federal licensing schemes. On the other hand, a holding that agency preemption of non-conflicting state law must be expressly set forth in regulations will not preclude federal agencies from seeking to pre-empt *conflicting* state laws on a case by case basis under the agency's rulemaking or adjudicatory procedures or in a judicial proceeding.

(2) Even assuming that implied preemption is ever appropriate for agency regulations, it should only be permitted when three standards are *all* met: when the subject matter is of national concern, when the agency has exhaustively regulated the subject *and, most importantly,* when state or local regulation clearly creates a factually established conflict with the purpose or implementation of the federal regulatory scheme.

In the context of assessing the preemptive effect of an agency's regulations, the court of appeals thus erred in giving equal weight to the "three tests" in *Pennsylvania v. Nelson.* Satisfaction of the first two tests, while plainly necessary, is not at all sufficient to justify implied preemption by a federal agency, as opposed to Congress. First, exhaustive rules governing any subject within an agency's jurisdiction is the norm and not the exception for agency regulation, and therefore, the existence of a "comprehensive regulatory scheme" cannot, in and of itself, be dispositive of an agency's preemptive intent. *See New York Dep't. of Social Services v. Dublino,* 413 U.S. 405 (1973). Second, uniform, minimum standards, in

and of themselves, should not be sufficient to establish preemption by regulation because they do not imply any intention to regulate exclusively. Reliance on either of these two factors alone—or in tandem—will cause courts to find preemption where it is not necessary to achieve any federal objectives.

Implied preemption by regulation is proper only if there is a clear factual basis for a court to conclude that local standards pose a real and serious conflict with the federal regulatory scheme. Such a conflict exists when it is impossible to comply with the state law without violating federal regulations or without utterly frustrating federal regulatory objectives. In this case, the goals of both the FDA and the County are congruent, and the court of appeals does no more than assert, without any specific analysis, that the federal goal of assuring a supply of healthy donors will be impaired by the County's ordinances. Its "analysis" of the purported conflict is wholly inadequate to justify nullifying a local government's effort to protect the public health by adopting standards that complement those of the FDA.

ARGUMENT

The preemption doctrine, which is derived from the Supremacy Clause of the Constitution, has traditionally involved the issue whether *Congress* has intended in a particular statute to exercise its supreme authority to regulate exclusively—without any state or local involvement. In ascertaining Congress' preemptive intent, this Court consistently has held that preemption is "compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose." *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977); *Fidelity Federal Savings & Loan, Ass'n. v. De La Cuesta,* 458 U.S. at 153. In addition, preemption is required whenever state law actually conflicts with a federal statute. 458 U.S. at 153.

While the standards for judging the preemptive effect of Congress' actions are well established, the court of

appeals did not hold that Congress expressly or implicitly intended to preempt Hillsborough County's Ordinances. The court held, instead, that the FDA through its regulatory scheme impliedly preempted local law. Although this Court has had relatively few occasions to examine the preemption doctrine as it relates to agency-created law, it nevertheless has established some clear rules.

It is well settled that when state law directly conflicts with a federal regulation then the Supremacy Clause of the Constitution requires that the federal regulation must prevail, just as if it were a federal statute. *See, e.g., Capital Cities Cable, Inc. v. Crisp*, —— U.S. ——, 104 S. Ct. 2694, 2703-2704 (1984); *Free v. Bland*, 369 U.S. 663, 668 (1962); *United States v. Shimer*, 367 U.S. 374, 385 (1961). It is also clear that, within its area of delegated authority, an administrative agency has power that is similar to Congress' to declare expressly a subject to be a matter of exclusive federal concern that will be governed solely by federal regulations.[10] By doing so the agency ousts all state laws, even those that may complement, rather than conflict with, federal law. *See, e.g., Capital Cities Cable, Inc. v. Crisp*, —— U.S. ——, 104 S. Ct. at 2700-2703; *Fidelity Federal Savings & Loan Ass'n. v. De La Cuesta*, 458 U.S. at 154.

---

[10] The powers are not identical. Congress is not obligated to provide specific reasons for its enactments, but the Administrative Procedure Act requires agencies to provide a statement of reasons to justify even informal rules. 5 U.S.C. § 553. Moreover, although the Court in *De La Cuesta* held that the agency's express decision to preempt state law is subject to the "arbitrary and capricious" standard of review applicable to other agency rules, the Court did not foreclose the possibility that action that might otherwise be permissible is arbitrary because its effect is to oust all state and local law on the subject. At a minimum, efforts to nullify state law should be subject to a searching inquiry into the agency's reasons for such an extraordinary assertion of its power. *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402 (1971).

The issue posed by this case is whether, or under what circumstances, it is appropriate for a court to find that an *agency*, as opposed to Congress, has *impliedly* preempted all state law, even that which is complementary to the federal scheme. The court of appeals in effect held that the standards in *Pennsylvania v. Nelson*, used by this Court to determine whether Congress implicitly has occupied the field and preempted all state law, apply with equal force to agency action. We submit that this holding is wrong. The Eleventh Circuit's decision involves a dramatic and wholly unwarranted extension of the preemptive power of administrative agencies and therefore this Court should reaffirm and clarify its holding in *De La Cuesta* that federal agencies can preempt state laws only when their intent is expressly set forth in the agency's regulations (part I, *infra*) or when there is a clear showing of a conflict between the federal regulations and state law (part II, *infra*).

I. The Preemption Of Non-Conflicting State Law By Agency Regulation Is Appropriate Only When The Federal Agency Has Expressly Indicated In Its Regulations Its Intention To Preempt State Law.

(A) The court of appeals did not find *any* evidence of *congressional* intent, either in the relevant statutes or their legislative history, to preempt state and local regulations concerning the plasmapheresis process.[11] It did not

---

[11] Nor is there any basis for such a holding. Congress made it clear in 42 U.S.C. § 263n, which is a companion provision of the Public Health Service Act that deals with federal health standards for electronic products, that it knew how to occupy the field of regulation when it felt the subject matter warranted it. That provision expressly states that no state or local government has authority to adopt any standard or to continue in effect any standard "which is not identical to the Federal Standard." 42 U.S.C. § 263n. The absence of any comparable language in 42 U.S.C. § 262, which was enacted at the same time, is compelling evidence that Congress never intended to preempt the field of biological product regulation, including the regulation of blood plasma.

find that the *congressional* scheme, which is embodied in a single, relatively short statutory provision, compelled the conclusion that Congress intended to occupy the field of plasmapheresis regulation.[12] The court of appeals did not find that local standards would undermine any *congressional* objective to assure nationwide uniformity for plasmapheresis procedures.[13] What it found instead was

---

[12] The court's assertion that blood is a matter of national concern is insufficient to show any implied *congressional* intent to preempt blood plasma regulation. Every subject about which Congress legislates is by definition a matter of national concern, but that cannot mean that every piece of legislation preempts the field and ousts all state law. *See Huron Portland Cement Co. v. Detroit*, 362 U.S. 440, 447 (1960) ("The mere possession of a federal license, however, does not immunize a ship from the operation of the normal incidents of local police power. . . ."); *De Canas v. Bica*, 424 U.S. 351, 360 n.8 (1976). Instead, the Court must consider whether the subject is *uniquely* a matter of federal concern. With this standard, the Court has held that laws dealing with subversives who try to overthrow the federal government involve uniquely federal concerns. *Pennsylvania v. Nelson*, 350 U.S. 497 (1956). Similarly, the Court has held that alien registration was a matter of unique federal concern because of Congress's primary authority to regulate immigration and foreign affairs. *Hines v. Davidowitz*, 312 U.S. 52 (1941). Because it also falls within the state's traditional power to promote health and safety, the regulation of blood plasma obviously does not implicate any uniquely federal concerns comparable to those in *Hines* and *Nelson*.

[13] Blood plasma is not a subject that so obviously requires a uniform national role that a court could fairly infer that *Congress* intended to oust state and local efforts to regulate donors. The Court has found that some statutory schemes regulating trains and ships or shipping preempt state law, because commerce would be adversely affected if standards or requirements other than those imposed by federal law could be imposed by every jurisdiction in which a train or ship passed or entered. *See, e.g., Ray v. Atlantic Richfield Co.*, 435 U.S. 151, 157-158 (1978); *Southern R. Co. v. Railroad Comm'n.*, 236 U.S. 439 (1917).

But the regulation of blood plasma at the source of its creation as a product does not create any obstacles for interstate commerce that might justify an inference that Congress would have intended the FDA's procedures to be exclusive. This is not an area of the

a substantial administrative *agency* scheme and an *agency-created* set of minimum standards for protecting donor safety. (J.S. App. A8-A9). Those findings do not, however, show Congress's intent and the court of appeals did not claim that they did. The most they logically could do is support a finding that Congress authorized the agency to exercise preemptive authority and that the *FDA* implicitly intended to occupy the field of plasmapheresis regulation. But, as we now show, this Court has required federal agencies to state "clearly" an intent to preempt, which should be read to mean that the agency must state expressly in the regulation that it intends to preempt state law.

(B) The court of appeals seems to have assumed that since "[f]ederal regulations have no less pre-emptive effect than federal statutes," *Fidelity Federal Savings & Loan Ass'n. v. De La Cuesta*, 458 U.S. at 151, the standards used to ascertain Congress' implied preemptive intent can be applied directly to agency action. But *De La Cuesta*, properly understood, stands for precisely the opposite proposition.

De La Cuesta involved the preemptive effect of a Federal Home Loan Bank Board regulation that expressly authorized federal savings and loans to include "due-on-sale" clauses in their mortages. Some states, including California, had declared such clauses illegal under state law. In disputes between a lender and a borrower in California, the California state courts had held that the state law was valid, in part, on the theory that federal regulations, in contrast to the statute pursuant to which they were promulgated, cannot preempt state law.

---

law "inherently requiring national uniformity." *Head v. New Mexico Bd. of Examiners*, 374 U.S. 424, 430 (1963). There is, therefore, nothing that makes the plasmapheresis process any more suitable for exclusive federal regulation than the quality of avocadoes. Compare *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132 (1963).

This Court's statement about the preemptive effect of federal regulations was made in response to the bald holding of the California courts that agency regulations cannot preempt state law. The Court easily rejected the state courts' holding, reaffirming that the Supremacy Clause embraced federal regulations. See *United States v. Shimer*, 367 U.S. 374 (1961); *Free v. Bland*, 369 U.S. 663 (1962).

But to hold that the preemptive effect of a regulation and a statute are the same is not to say that the legal standards for finding preemption are or should be identical. Indeed, the Court implicitly recognized this point in *De La Cuesta* when it set out specifically the standards applicable to deciding when the regulations, as opposed to an Act of Congress, preempt state law. On that issue, the Court held that preemption is appropriate only if an agency "clearly" intends to preempt a specific subject, such as the availability of due-on-sale clauses in home mortgages, and if the agency was delegated adequate authority to regulate that particular subject. 457 U.S. at 154. In *De La Cuesta*, this Court focused on the *express* intent of the Federal Home Loan Bank Board to preempt all state regulation. *Ibid.* The Court conditioned its holding, that the Board's regulation ousted state law, on the existence of a clear regulatory statement that the Bank meant to eliminate all state efforts to regulate due-on-sale practices of federal savings and loans. *Id.* at 159. *De La Cuesta* thus requires a clear expression of administrative intent to preempt all state efforts, including non-conflicting laws, to regulate the same subject.

Just last Term, the Court followed precisely the same analysis in declaring Oklahoma's statutory restrictions on cable television advertising to be preempted by regulations of the Federal Communications Commission. *Capital Cities Cable, Inc. v. Crisp*, —— U.S. ——, 104 S. Ct. at 2700-2703. Again the Court undertook to determine whether "the FCC has resolved to pre-empt an area of cable television regulation" (*id.* at 2701) and declared the State's provisions

invalid because they "interfered with a regulatory area that the Commission has *explicitly* pre-empted." *Id.* at 2703 (emphasis added). Thus, this Court has limited the doctrine of preemption of the field when applied to agency regulation—as opposed to congressional action—to situations where the agency expressly declares what area of regulation it intends should be off limits to any state or local activity. *See California v. Zook*, 336 U.S. 725, 737 (1949) ("one would expect the federal agency to be specific if it intended to supersede state laws").

(C) A rule limiting the authority of federal agencies to preempt nonconflicting state law to situations where preemptive intent is clearly expressed in the regulation itself is supported by sound policies.[14] To understand why a federal agency's authority should be so limited, it is important to appreciate the scope of the power granted by *De La Cuesta*. Within the confines of the power granted to them by Congress, agencies have very broad discretion to preempt state law.[15] *De La Cuesta*

---

[14] Nor is a requirement of a clear statement by the federal government of its intent to intrude on traditional state authority unprecedented. This Court in other cases where federal-state relations were implicated has refused to imply that Congress, much less a federal agency, intended to invade state interests. *See, e.g., Parker v. Brown*, 317 U.S. 341, 351 (1943) ("In a dual system of government in which, under the Constitution, the states are sovereign, save only as Congress may constitutionally subtract from their authority, an unexpressed purpose to nullify a state's control . . . is not lightly to be attributed to Congress"); *Pennhurst State School and Hospital v. Halderman*, 451 U.S. 1, 16 (1981) ("Because such legislation imposes congressional policy on a State involuntarily, and because it often intrudes on traditional state authority, we should not quickly attribute to Congress an unstated intent to act. . . .").

[15] Although Justice O'Connor pointed out in her concurring opinion in *De la Cuesta* (458 U.S. at 172), that the delegation of authority to the Bank Board to regulate federal savings and loans "does not permit the Board to pre-empt the application of all state and local laws to such institutions," it is nevertheless clear that the Board, and every other agency with a relatively broad delegation of

and *Capital Cities Cable*, however, implicitly contain at least one reasonable limitation on that power—it must be exercised expressly and specifically. Because of this requirement, federal agencies, which are not representative institutions, can be held at least somewhat accountable when they act to nullify state law.

The non-representative nature of federal regulatory agencies, as opposed to Congress, is a critical factor in setting appropriate standards for determining when preemption by regulation is appropriate. While the needs and interests of the state can perhaps be protected politically when the final decision is made by Congress, there is no similar political protection when fundamental decisions emanate from administrative agencies, which are generally intended to be relatively immune from direct political pressures in order to carry out Congress' will. Thus, the political relationship between Congress and the states created in the Constitution itself which the Court can rely upon to check *Congress'* excesses when it regulates matters traditionally subject to state and local government, *see Garcia v. San Antonio Metropolitan Transit Authority*, No. 82-1913 (Feb. 19, 1985), slip op. at 22, is completely missing when agencies are the source of preemptive decisionmaking authority. It is therefore necessary and appropriate for the Court to impose additional checks on agencies before holding that their regulatory actions can oust complementary state and local exercises of their police powers.

A rule requiring express preemption by agencies at least guarantees state and local officials an opportunity to engage the agency in a dialogue as to whether preemption of local law is in the public interest. Under the standard employed by the Eleventh Circuit, by contrast, federal agencies wishing to oust state authority would be able to enact a substantial number of minimum standards

---

authority, has extraordinary power under *De La Cuesta* to nullify state law.

without mentioning in any notice to the public that the agency intends thereby to eliminate complementary state and local regulation. In this way, agencies could minimize the public comments, especially from state and local officials, that would otherwise be forthcoming if it were clear the agency intended to assert a particular power exclusively. This is no way to ensure responsible decision making by administrative agencies.

The Eleventh Circuit's rule also will encourage unnecessary litigation. Private interests currently being regulated by federal law will have a strong economic incentive to go to court to try to halt any local effort to impose any additional requirements on them. Under the vague standards adopted by the court of appeals for determining whether a federal agency has impliedly preempted state law, these private interests will very likely succeed, as appellees have here, in delaying the implementation of local laws designed to protect public health and safety.[16]

It is completely anomalous to have a rule for preemption that allows private parties to argue successfully that federal agencies, without even knowing it, have nullified state laws that are designed to protect the public health and welfare, which this Court has recognized "is a vital part of a state's police power." *Barsky v. Bd. of Regents*, 347 U.S. at 449. Probably no one was more surprised than FDA officials to learn that the agency's minimum

---

[16] The court of appeals' implied preemption doctrine will almost certainly retard state and local efforts to adopt new public health and safety standards in areas that are presently subject to federal regulation. Not very many local jurisdictions will be willing to adopt standards and defend them all the way to this Court under the vague implied preemption standards employed by the court of appeals. This, of course, means that local experimentation with new standards will be curtailed and useful experience based on such standards will be lost. *See California v. Zook*, 336 U.S. 725, 737 (1949); *New State Ice Co. v. Liebmann*, 285 U.S. 262, 310-311 (1932) (Brandeis, J., dissenting); *Anderson v. Dunn*, 6 Wheat. 204, 226 (1821).

standards had the effect of prohibiting all state and local efforts to adopt additional safety requirements for plasmapheresis to deal with special problems unique to a particular locality. Respect for state and local initiative demands that preemption not be the result of accident or misunderstanding.[17]

On the other hand, it is perfectly reasonable to require federal agencies to act responsibly and indicate clearly when and how they plan to exercise exclusive control over a particular subject. With the flexibility inherent in the notice and comment procedures, 5 U.S.C. § 553, agencies can notify the public about their plans, receive comments about the propriety of preemption and then carefully tailor the final regulations to protect areas that demand an exclusive federal presence.

Nor is it necessary for the Court to retain an implied preemption of the field doctrine for administrative agencies to deal with the issue posed by the "third test" in *Pennsylvania v. Nelson*, *viz.*, "whether the enforcement of state law presents a serious danger of conflict with the administration of the federal program." J.S. App. A10, citing, 350 U.S. at 505. Since agencies that have the authority to create minimum standards for an industry also will have the authority to preempt state law, they can respond specifically to any "serious dangers" that they

---

[17] There is at least some risk that the implied preemption doctrine when applied to Congress' enactments would lead to similar problems, i.e., a court could find that Congress occupied the field even when Congress did not so intend. But the differences between Congress and administrative agencies make this problem much less likely when courts consider the preemptive effect of federal statutes. Congress ordinarily does not pass legislation that is so pervasive that it permits the clear inference that preemption was intended. Agencies, by contrast, almost always adopt exhaustive regulations. Moreover, it is much less reasonable to expect Congress to act with the same precision as an agency. By contrast, it is a relatively simple matter for a federal agency to adopt a regulation that clearly and expressly states what the agency intends to preempt.

perceive from state and local regulation on a case-by-case basis. If they do not perceive any danger to their program, it makes no sense for a federal court to find that one exists. Again, respect for state and local authority demands that agency preemption not be implied by federal courts, but rather be permitted only when the agency itself expresses a clear intent to preempt the field, which is accompanied by a factually-supported explanation of the clear need to oust non-conflicting state and local attempts to protect public health and safety.

In light of what we have argued, it is plain that the decision below must be reversed. The court of appeals itself held that neither Congress, expressly or implicitly, nor the FDA expressly preempted the field of plasmapheresis regulation. Since these are the only valid ways for federal law to preempt non-conflicting state law, the court of appeals erred in striking down the ordinances *completely* without considering whether the district court was correct in holding that there are no specific conflicts between the ordinances and the FDA's regulations (see pages 24-27, *infra*).

II. Implied Agency Preemption Should Be Permitted Only On The Basis Of A Clear Showing That State Or Local Law Conflicts With The Purpose Or Implementation Of The Federal Regulatory Scheme.

In its opinion, the court of appeals applied to agency regulation the three tests for preemption this Court discussed in *Pennsylvania v. Nelson*, for determining whether Congress *implicitly* preempted state law with respect to the criminal prosecution of subversives. J.S. App. A9-A10). First, the court of appeals asked whether the federal scheme is pervasive, and concluded it is because the FDA has a relatively extensive set of regulations concerning plasmapheresis. Second, the court asked whether the federal interest in the subject matter is so dominant that enforcement of state laws can be assumed to be inappropriate, and concluded it is because "blood is

an area of national concern." Third, the court asked whether enforcement of state law "presents a serious danger of conflict with the administration of the federal program," and concluded it does because the County's Ordinances might undermine the goal of maintaining a continued supply of healthy blood donors. (*Ibid.*).

The court of appeals erred, however, in its application of *Nelson* to federal *regulations*. The *Nelson* tests are simply not very meaningful when applied to federal agencies as opposed to Acts of Congress. While the first two tests are necessary in order to preempt state law impliedly, they clearly are not sufficient because they are likely to be satisfied by virtually any regulatory regime. The key *Nelson* factor which justifies *implying* preemption by agency regulations is whether state law actually conflicts with the purpose or implementation of the federal regulations. But even this standard must be applied carefully—implied preemption by regulation should occur only when the record clearly demonstrates a real conflict.

(A) The court of appeals erred initially in attaching any independent preemptive significance to the first two *Nelson* tests as they apply to agencies. First, the fact that an administrative agency has adopted "pervasive" regulations is hardly a basis for inferring preemptive intent.[18] As anyone who has ever perused the Code of Federal Regulations can attest, agency regulation by its nature tends to be fairly detailed in order to provide relatively clear guidance to regulated entities.

Indeed, this Court has held that, even when Congress itself treats a subject in exacting detail, an automatic inference of preemption is not waranted. *New York Dep't. of Social Services v. Dublino*, 413 U.S. at 415. As the Court explained "[g]iven the complexity of the matter addressed by Congress in the federal work incentive

[18] Obviously, the absence of a pervasive scheme is powerful evidence that an agency did not intend impliedly to oust complementary state and local law.

program, a detailed statutory scheme was both likely and appropriate, completely apart from any question of preemptive intent." *Ibid.*; *see De Canas v. Bica*, 424 U.S. at 359.

It would grossly distort the preemption doctrine, which presumes that state laws are valid unless federal law clearly requires otherwise,[19] to hold that simply because an agency has adopted a substantial number of detailed regulations concerning a subject, that area is rendered off limits to complementary state and local law designed to protect the public health and safety. Under the reasoning of the court below, whenever a federal agency enacted comprehensive minimum standards for an industry, it would have to declare expressly that it did *not* intend its regulations to be exclusive in order to eliminate the inference of preemptive intent that the court of appeals found here.

The second *Nelson* factor, whether the subject is a matter of "dominant" national concern, is also an inappropriate measure of implied regulatory preemption. It is inconceivable that any subject that Congress itself does not regard as a matter of dominant national concern can become such solely by virtue of how the agency regulates it. Certainly, this is not such a case.

The court of appeals relied largely on administrative statements indicating that the supply of blood is a matter not of "dominant" national concern, but only of "national concern." But the fact that a federal agency has promulgated regulations pursuant to a federal statute means that the subject matter is per se of concern to the federal government. Moreover, it will be the unusual case when a litigant cannot cite broad language in the Federal Register explaining that the subject of

[19] *See, e.g., Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981); *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977). *Huron Portland Cement Co. v. Detroit*, 362 U.S. 440, 445 (1960); *Schwartz v. Texas*, 344 U.S. 199, 202-203 (1952); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

the regulation and the need for some minimum standards is a matter of national concern. Otherwise, there would be no point in proposing regulations. To imply preemption of the field from such statements would therefore unduly expand areas of preemption. There are a host of subjects that are proper concerns of the federal government that are equally appropriate for local complementary regulations; but the second *Nelson* test wholly fails to recognize any of them.

(B) The crucial issue in determining implied preemption by federal regulation must be the third *Nelson* test—whether the state and local regulations conflict with the purpose or implementation of the federal regulatory regime. *See Michigan Canners & Freezers Ass'n. v. Agricultural Marketing and Bargaining Bd.*, —— U.S. ——, 104 S. Ct. 2518 (1984); *Campbell v. Hussey*, 368 U.S. 297, 301 (1961). The court of appeals did find a conflict between the two schemes, but its cavalier handling of this issue without any serious analysis of the "conflict" is completely inadequate. Principles of federalism require the Court to uphold the County's exercise of its police power unless there is an inevitable clash between the County's purpose and the FDA's or if the obligations imposed by the County create conflicting duties or otherwise impair implementation of the agency's regulatory mission. But in this case the purposes of the two schemes are completely compatible and the County imposes no obligation on anyone that will interfere with the FDA's ability to regulate plasmapheresis centers under its regulations. We will analyze the relationship between the purposes first and then discuss the effect of the County's scheme on the implementation of the federal program.

(1) The FDA's regulations expressly state that they are intended only to protect the vendor's health and safety and to assure a supply of pure blood plasma. *See* page 3, *supra*. These goals are fully consistent with the goals of the County's Ordinances. *See* page 6, *supra*. All the County's Ordinances do is fill a serious void in the federal regulatory protections and thereby better assure that the donors' safety is protected and that each donor supplies a safe quality and quantity of blood plasma in order to protect the employees of the plasmapheresis centers. It should be the rare case when a state program is declared invalid when it has not merely complementary goals, but goals that are virtually identical to the federal administrative scheme. *See Exxon Corp. v. Governor of Maryland*, 437 U.S. 117, 132 (1978); *California v. Zook*, 336 U.S. at 737.[20]

The court of appeals asserts, without any real evidence, that the County's ordinances will adversely affect the national goal of "guaranteeing a continued supply of healthy donors. . . ." (J.S. App. A11). This is the only finding of a conflict between federal and local goals that even arguably supports implied preemption. But the court of appeals made no effort to explain how these Ordinances could possibly limit the supply of healthy donors. They might limit the supply of *unhealthy* donors, but that is fully consistent with the purposes of the FDA's regulations. Certainly, principles of comity between the federal government and state and local governments require a court to provide a clearer explanation based on a fuller factual foundation of how the purposes of local laws con-

[20] The court of appeals assumes from the existence of minimum standards in the FDA's regulations that these standards were intended to be exclusive. But the goal of uniformity in minimum standards is weak, if any, evidence of a federal purpose to set exclusive standards. Simply because the FDA has concluded that it should enact certain minimum requirements nationwide to protect donor safety does not mean that the FDA intended to protect the plasmapheresis centers from any additional burdens imposed by local officials that are intended to further aims that are identical to the FDA's program. Thus, whether the County's ordinances undermine "uniformity" is, in and of itself, no basis for concluding that the ordinance poses a real danger to the underlying *federal objective*, which is protecting safety and health. *See Florida Lime & Avocado Growers, Inc. v. Paul, supra*, 373 U.S. at 147-148.

flict with the purposes of federal law than the court of appeals has offered here, before state and local attempts to provide non-conflicting standards to protect public health and safety can be nullified. *Huron Portland Cement Co. v. Detroit*, 362 U.S. at 446.[21]

(2) Nor is there any basis for concluding that the federal and county programs clash in a way that will interfere with the FDA's implementation of its regulations. Of course, if a County requirement actually conflicted with an FDA regulation, then it would be preempted. But there are no conflicts in this case.

To the extent the two regulatory schemes overlap, the County imposes somewhat greater obligations on the plasmapheresis centers than does the FDA. See pages 6-7, *supra*. But it is certainly possible for the centers to comply with both laws. Similarly, the County imposes an additional obligation on the donors, but requiring identification cards and a breathalyzer test does not conflict with the FDA's regulations in any way that would render it impossible for the underlying purposes of federal law to be achieved fully.[22] These matters are simply not addressed by federal law. Compare *Exxon Corp. v. Governor of Maryland*, 437 U.S. at 131. Finally, the County will provide an additional set of inspections,

[21] It is not at all clear precisely how the court of appeals believes that the County's standards will undermine the goal of guaranteeing a supply of healthy donors. To the extent that the court was concerned about the basic viability of the plasmapheresis centers, its conclusion is unsupported by the findings of the district court, which concluded that appellee's assertion of financial harm caused by the Ordinances was too speculative to be credited (J.S. App. A15-A16). The court of appeals did not even address this finding much less hold that it was clearly erroneous. Moreover, it is not the purpose of the FDA's regulations to protect plasmapheresis centers from the ordinary expenses of doing business within a particular locality.

[22] *See Hines v. Davidowitz*, 312 U.S. at 67-68; *Jones v. Rath Packing Co.*, 430 U.S. at 526, 540-541; *De Canas v. Bica*, 424 U.S. at 363.

but there is no reason to assume without evidentiary support that the County would interfere in any way with the FDA's enforcement efforts. Both sets of regulations therefore can co-exist in harmony, and accordingly, the court of appeals erred in holding the County's Ordinances unconstitutional under the Supremacy Clause.[23]

[23] The Solicitor General in his *amicus* brief at the jurisdictional stage of this case suggested (Br. at 10-12) that the Ordinance's "Certificate of Good Health" requirement for all vendors may conflict with a special FDA regulation that allows some donors who are hepatitis-reactive to sell blood for the purpose of manufacturing the vaccine used to prevent hepatitis. *See* 21 C.F.R. 610.41, 640.75. But there is no reason for this Court to speculate about this issue in this appeal. It is clear that appellee's plasmapheresis center is not a specialized facility licensed by the FDA under 21 C.F.R. 640.75, to accept blood from hepatitis-reactive donors. As the court of appeals explained, "[t]he staff physician rejects any candidate who has a history of viral hepatitis" and appellee's center "destroys the unit of plasma" if it is contaminated. J.S. App. A4. Thus, appellee has no standing to complain about the effect of the "Certificate of Good Health" requirement as it might apply to a different type of center.

Moreover, it is hardly clear that Ordinance #80-12 was intended to preclude specialized plasmapheresis centers from operating within the County. The Ordinance expressly incorporates 21 C.F.R. 640.75, as one of the provisions of the FDA regulations that the County will enforce. *See* Ordinance #80-12, § 15; J.S. App. A38-A39 (incorporating Section 640 *et seq.* of FDA's regulations). That is the provision that allows the FDA to license special facilities. Since the County has authorized such facilities, it would seem quite unlikely that it would interpret its Ordinance so as not to allow anyone to donate blood to them. Under these circumstances, for the Court to strike down the County's "Certificate of Good Health" requirement as applied "would be to ignore the teaching of this Court's decisions which enjoin seeking out conflicts between state and federal regulation where none clearly exists." *Huron Portland Cement Co. v. Detroit*, 362 U.S. at 446.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted,

BENJAMIN W. HEINEMAN, JR.
CARTER G. PHILLIPS
SIDLEY & AUSTIN
1722 Eye Street, N.W.
Washington, D.C. 20006
(202) 429-4000

JOYCE HOLMES BENJAMIN *
STATE AND LOCAL LEGAL CENTER
444 N. Capitol Street, N.W.
Suite 349
Washington, D.C. 20001
(202) 638-1445
Counsel for the Amici Curiae

* Counsel of Record

(6)

No. 83-1925

In the Supreme Court of the United States

OCTOBER TERM, 1984

HILLSBOROUGH COUNTY, FLORIDA, ET AL., APPELLANTS

v.

AUTOMATED MEDICAL LABORATORIES, INC.

ON APPEAL FROM THE
UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

REX E. LEE
Solicitor General

RICHARD K. WILLARD
Acting Assistant Attorney General

KENNETH S. GELLER
Deputy Solicitor General

PAUL J. LARKIN, JR.
Assistant to the Solicitor General

MARGARET E. CLARK
IRENE M. SOLET
Attorneys

Department of Justice
Washington, D.C. 20530
(202) 633-2217

40pp

QUESTION PRESENTED

Whether Hillsborough County Ordinances 80-11 and 80-12 and their implementing rules and regulations pertaining to the collection of blood plasma from paid donors are preempted by regulations adopted by the Food and Drug Administration governing blood and blood products, including blood plasma and plasmapheresis.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases:

Cases—Continued: Page

Cases—Continued: Page

Constitution, statutes, rules and regulations:

In the Supreme Court of the United States

OCTOBER TERM, 1984

No. 83-1925

HILLSBOROUGH COUNTY, FLORIDA, ET AL., APPELLANTS

v.

AUTOMATED MEDICAL LABORATORIES, INC.

ON APPEAL FROM THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

INTEREST OF THE UNITED STATES

The question presented by this case is whether the regulations promulgated by the Food and Drug Administration (FDA) governing blood, blood components, blood products, and plasmapheresis preempt Hillsborough County, Fla., Ordinances 80-11 and 80-12 (Nov. 26, 1980) and their implementing Rules and Regulations. The United States, through the FDA, has the primary responsibility for ensuring the safety, purity, and potency of blood, blood components, and blood products distributed in interstate and foreign commerce and thus has a substantial interest in ensuring that the federal regulations governing these matters are construed in a manner that advances, rather than impedes, their objectives.

STATEMENT

A. The Federal Regulatory Scheme

The Public Health Service Act, 42 U.S.C. 262 *et seq.*, and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 *et seq.*, authorize the Department of

Health and Human Services (HHS) to regulate blood and blood products as biological products (42 U.S.C. 262)[1] and as drugs (21 U.S.C. 321(g)(1)).[2] Under Section 351(a) of the Public Health Service Act, 42 U.S.C. 262(a), manufacturers and vendors of biological products, including blood products and their derivatives, must be licensed by the Secretary of

[1] Section 351 of the Public Health Service Act, as amended by Section 291 of the Heart Disease, Cancer, Stroke and Kidney Disease Amendments of 1970, Pub. L. No. 91-515, 84 Stat. 1308, 42 U.S.C. 262, forbids the manufacture or sale in interstate or foreign commerce of any "blood, blood component or derivative" without a license from the Secretary of HHS. See 39 Fed. Reg. 18614 (1974); 38 Fed. Reg. 2965 (1973). Blood plasma is subject to the Act. *United States* v. *Steinschreiber*, 218 F. Supp. 426, 427-428 (1962), supplemented, 219 F. Supp. 373 (S.D.N.Y. 1963), aff'd, 326 F.2d 759 (2d Cir.) (per curiam), cert. denied, 376 U.S. 962 (1964); *United States* v. *Calise*, 217 F. Supp. 705, 708-709 (S.D.N.Y. 1962); see page 15 note 14, *infra*.

[2] Section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321(g)(1), defines a "drug" to include "(A) articles recognized in the official United States Pharmacopeia * * * and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man." Blood was first listed in the United States Pharmacopeia in 1955 (38 Fed. Reg. 2965 (1973)), and it has been included in every subsequent edition. Blood, blood components, and blood products also serve the therapeutic purposes identified in the statute and thus qualify as "drugs" for that reason as well. *Ibid.*; see also 39 Fed. Reg. 18614 (1974); *Blank* v. *United States*, 400 F.2d 302, 305-306 (5th Cir. 1968); *United States* v. *An Article of Drug* * * * *Bacto-Unidisk*, 392 F.2d 21, 23 (6th Cir. 1968), rev'd on other grounds, 394 U.S. 784 (1969); *United States* v. *Calise*, 217 F. Supp. 709; cf. *United States* v. *An Article of Drug* * * * *Bacto-Unidisk*, 394 U.S. 784, 793 (1969) ("[v]iewing the structure, the legislative history, and the remedial nature of the Act, we think it plain that Congress intended to define 'drug' far more broadly than does the medical profession").

HHS. Licenses are issued only upon a showing that the manufacturer's or vendor's establishment and products meet certain safety, purity, and potency standards established by the Secretary. 42 U.S.C. 262(d). HHS is authorized to inspect such establishments for compliance as it sees fit. 42 U.S.C. 262(c).

Pursuant to Section 351, 42 U.S.C. 262, the Food and Drug Administration's Office of Biologics Research and Review, as the designee of the Secretary,[3] regulates various types of blood products and blood banking activities, including blood plasmapheresis procedures. 21 C.F.R. Pts. 600, 601, 606, 607, 610, 640.[4] Under 21 C.F.R. Part 640, Subpart G, the FDA has established standards for plasma collected by plasmapheresis. 21 C.F.R. 640.60-640.76. These standards were adopted, and are revised from time to time, to ensure the safety, purity, and potency of the final products derived from plasma[5] and to protect plasmapheresis donors from possible abuses ranging from the collection of excessive quantities of plasma to the use of medical or collection procedures that could endanger a donor's health. See 39 Fed. Reg. 26161 (1974). The regulations require, inter alia, that a plasma center obtain the informed consent of donors before plasmapheresis is performed and that a

[3] Pursuant to Section 361 of the Public Health Service Act, 42 U.S.C. 264, and under the authority delegated to him by the Secretary (21 C.F.R. 5.10), the Commissioner of Food and Drugs is authorized to promulgate regulations to implement the Act.

[4] Plasmapheresis is defined as "the procedure in which blood is removed from the donor, the plasma is separated from the formed elements and at least the red blood cells are returned to the donor." 21 C.F.R. 606.3(e); see also J.S. App. A3, A14.

[5] Plasma derivatives include such products as hepatitis vaccine, albumin, and antihemophilic factor. See, *e.g.*, 21 C.F.R. 610.41, 640.50, 640.80.

licensed physician both examine a potential donor before he or she is accepted and be present on the premises while the procedure is being performed. 21 C.F.R. 640.61-640.63.[6] The regulations establish minimum standards for donor eligibility, for conducting plasmapheresis, and for processing, storing, and labeling plasma units obtained during the procedure. 21 C.F.R. 640.63, 640.65, 640.68, 640.70. Recordkeeping requirements are also imposed. 21 C.F.R. 640.72. The Director of the Office of Biologics Research and Review has the power to approve variances from any of the requirements of Subpart G. 21 C.F.R. 640.75.

B. The Hillsborough County Ordinances And Regulations

In November 1980, Hillsborough County, Florida, adopted County Ordinances 80-11 and 80-12 (J.S. App. A29-A39), which govern the licensing and operation of commercial blood plasma donor centers. Ordinance 80-11 imposes a license fee on plasmapheresis centers, while Ordinance 80-12 "provide[s] a system for the registration and identification of and the gathering of medical data applicable to Commercial Blood Plasma Vendors as being in the common interest of the health of the people of Hillsborough County" (J.S. App. A32-A33). In addition to incorporating by reference the FDA's blood plasma regulations (*id.* at A38-A39), Ordinance 80-12 imposes certain additional donor testing and recordkeeping requirements not contained in 21 C.F.R. Part 640, Subpart G. Among other things, Ordinance 80-12 requires that plasma donors be issued county identification cards that restrict them to donating at one

[6] The FDA has construed those regulations to mean that a physician may be constructively on the premises if he is able to arrive within 15 minutes after being called. See FDA, *Instruction Booklet for Plasmapheresis Inspection Checklist and Report, Form FDA 2722*, at 1-2 (Sept. 1981).

particular center; it also requires that each donor be tested for hepatitis prior to registration[7] and be given a breath analysis for alcohol content before each plasma donation. Ordinance 80-12, §§ 4, 6(A) and (D), 7 (J.S. App. A33-A34, A35-A36). The County has issued Rules and Regulations to implement the ordinances (*id.* at A40-A42). Together, the ordinances and regulations impose a variety of requirements upon paid blood plasma donors and commercial blood plasma centers that are not found in the FDA's blood plasma regulations.

C. The Proceedings Below

1. Appellee Automated Medical Laboratories, Inc. (AML) is a Florida corporation that operates, through subsidiary corporations, eight blood plasma centers in the United States, including Tampa Plasma Corporation (TPC) in Hillsborough County (J.S. App. A14). TPC collects blood plasma from paid donors by plasmapheresis (*ibid.*).[8] Following Hillsborough's adoption of Ordinances 80-11 and 80-12, appellee filed this action against the County and its health department in the United States District Court for the Middle District of Florida, challenging, on several grounds, the constitutionality of the Ordinances and the Rules and Regulations adopted to implement them. In November 1982, following a bench trial, the court issued an opinion sustaining all but one aspect of the ordinances and regulations (J.S. App. A13-A19).

The district court found no evidence of "express congressional intent to occupy the entire field of as-

[7] Under federal regulations, testing for hepatitis-positive plasma is performed after plasmapheresis is completed. See 21 C.F.R. 640.67, 640.75.

[8] The steps that TPC follows are described in the opinions below. See J.S. App. A3-A4, A15; see also 1 Tr. 27-34.

suring high standards of practice in plasmapheresis" and concluded that the ordinances supplement the federal regulations, rather than conflict with them (J.S. App. A17). The court also held that the ordinances did not violate the Equal Protection Clause of the Fourteenth Amendment and that most of the challenged provisions did not impermissibly burden interstate commerce (J.S. App. A17-A18). With respect to the breathalyzer requirement, however, the court held that the County had not demonstrated that such a provision would serve the public interest to any greater degree than the federal regulations (*id.* at A19). Accordingly, the court held that the provisions relating to that requirement (Section 7 of Ordinance 80-12 and Section 4 of the implementing Rules and Regulations (J.S. App. A35-A36, A41)) impermissibly burdened interstate commerce and were thus invalid (*id.* at A19).

2. The court of appeals affirmed in part and reversed in part. The court held that the FDA's blood plasma regulations preempted all provisions of the County's ordinances and regulations (J.S. App. A1-A12). The court of appeals first noted that the federal regulatory scheme was "comprehensive" and stated that its "pervasiveness * * * makes it reasonable to infer that Congress [*sic*: the FDA] left no room for local ordinances to supplement it" (*id.* at A8-A9). The court also concluded, based on statements by the FDA regarding the establishment of a National Blood Policy, that the field of plasmapheresis was one in which the federal interest was dominant over any state or local interest (*id.* at A9-A10). Finally, the court ruled that the additional requirements imposed on plasma centers by the County's ordinances were "burdensome and expensive" and would interfere with "the national blood policy of promoting uniformity and guaranteeing a continued supply of healthy donors" (*id.* at A11).[9]

SUMMARY OF ARGUMENT

Pursuant to its statutory authority, the FDA has promulgated comprehensive regulations governing the collection of blood and blood components and the manufacture of blood products. Among those regulations are rules governing plasmapheresis, the process by which whole blood is removed from a donor, blood plasma is separated from the donor's whole blood, and the remaining blood components are returned to the donor. The purpose of the FDA regulations is to establish the nationwide standards necessary to provide an adequate supply of safe, pure, and potent blood, blood components, and blood products as well as to protect the health of blood donors. Hillsborough County has also enacted a regulatory scheme governing these matters, which, in addition to incorporating the federal regulations, imposes additional licensing, certification, recordkeeping, reporting, and inspection requirements upon vendors and donors within the County.

In this case, the court of appeals held that the Hillsborough County regulatory scheme was implicitly but completely preempted by the federal regulations. The reasons given by the court for its ruling are unsound, however. The federal regulations do not expressly foreclose any supplementary state or local regulation of this subject, and, with one potential ex-

---

[9] Because of the court of appeals' preemption ruling, the court declined to decide whether the Hillsborough County ordinances and regulations, in whole or in part, violated the Commerce Clause or the Equal Protection Clause (J.S. App. A12). Were the Court to reverse the judgment of the court of appeals, these issues would be open on remand. The United States takes no position on these questions.

ception, the Hillsborough ordinances and regulations do not conflict with the FDA's regulations or interfere with federal policies in this area. Thus, while the FDA does not endorse the Hillsborough County regulatory scheme as a matter of policy and may someday decide to preempt such local regulations if their widespread adoption threatens to hamper the agency's ability to assure that an adequate supply of blood plasma is available to meet the nation's medical and scientific needs, it is the position of the FDA that this particular local regulatory scheme is not wholly superseded by federal law. Accordingly, aside from one provision that may conflict with the FDA's regulations and would therefore be preempted, the judgment of the court of appeals should be reversed.

1. Hillsborough Ordinances 80-11 and 80-12 and their implementing Rules and Regulations are not explicitly preempted by any federal statute or regulation. Two federal statutes, the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act, empower the FDA to regulate blood, blood components, and blood products, but neither Act expressly forecloses supplementary state or local regulation of plasmapheresis or can reasonably be construed to establish a federal monopoly over this field. Nor do the federal regulations governing this subject expressly preempt supplementary regulation of the type enacted by Hillsborough County or imply that the federal rules shall be the sole standards governing this field. The court of appeals was thus correct in ruling that neither Congress nor the FDA expressly intended to displace state and local authority in this area.

In fact, the FDA expressly disclaimed any intent to oust the states and local governments from the plasmapheresis field at the time the FDA originally adopted the plasmapheresis regulations at 21 C.F.R. Part 640. That contemporaneous statement of the

agency's intent regarding the proper scope of its own regulations is dispositive of the issue presented by this case.

2. The court of appeals thus erred in ruling that the FDA's regulations implicitly but completely displace the Hillsborough regulatory scheme. None of the reasons given by the court of appeals for finding that the Hillsborough ordinances and rules were implicity preempted is sufficient to justify complete preemption. The comprehensive scope of the FDA's regulations is the product of the FDA's dual goals of protecting product and donor safety as well as the complex and technical nature of the subject matter, rather than the agency's intent to preempt state law. Moreover, while the agency has the primary responsibility for regulating this subject on a nationwide basis and has adopted regulations to ensure that the nation's medical and scientific needs are fully met, the field of blood plasma regulation is not one in which national policies will inevitably be disrupted if the states and local governments also share in the effort to protect the public health. Finally, the Hillsborough ordinances and regulations, with one exception, do not at this time impose requirements that conflict with those established by federal law or impede the federal government from accomplishing stated federal goals. Complete preemption is thus unjustified.

3. The Hillsborough ordinances and regulations may be preempted in one respect. Section 6(D) of Ordinance 80-12 and Section 2.B of the implementing Rules and Regulations forbid plasma donors from undergoing plasmapheresis until an examining physician has issued a "Certificate of Good Health" as required by the FDA's regulations. However, the FDA authorizes specific plasmapheresis facilities to collect blood from donors who could not receive such a certificate, in order to produce certain vaccines and

diagnostic products. 21 C.F.R. 610.41, 640.75. To that extent, the Hillsborough regulatory scheme may conflict with the authority granted specific plasmapheresis centers by the FDA's regulations.

Appellee appears to lack standing to raise this issue, however, because the complaint does not allege that either appellee or its subsidiary operating in Hillsborough County has received an exemption from the FDA to collect blood from donors with a history of hepatitis. In addition, the County's regulations may be intended to incorporate the FDA's regulations that allow plasmapheresis centers to obtain an exemption. If so, there would be no conflict between the federal regulations and the County's regulatory scheme, and preemption would be unjustified.

ARGUMENT

I. THE HILLSBOROUGH COUNTY ORDINANCES AND REGULATIONS ARE NOT WHOLLY PREEMPTED BY FEDERAL LAW

A. Introduction

1. It is a familiar and well-established principle that the Supremacy Clause of Article VI, Clause 2, invalidates state laws that "interfere with, or are contrary to" federal law. *Gibbons* v. *Ogden*, 22 U.S. (9 Wheat.) 1, 211 (1824). Under the Supremacy Clause, federal law may supersede state law in several different ways. First, when acting within constitutional limits, Congress is empowered to preempt state law by so stating in express terms. *Jones* v. *Rath Packing Co.*, 430 U.S. 519, 525 (1977). In the absence of express preemptive language, Congress's intent completely to preempt state law in a particular area may be inferred because the scheme of federal regulation is so comprehensive as to make reasonable the inference that Congress "left no room" for supplementary state regulation. *Rice* v. *Sante Fe Elevator*

Corp., 331 U.S. 218, 230 (1947). Complete preemption will likewise be inferred where the field is one in which the federal interest is so dominant that the federal system will preclude enforcement of state laws on the same subject. *Fidelity Federal Savings & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141, 153 (1982). Finally, even where Congress has not completely displaced state regulation in a specific area, state law is preempted to the extent that it actually conflicts with federal law, either because it proves impossible to comply with federal and state law simultaneously (*Florida Lime & Avocado Growers, Inc.* v. *Paul*, 373 U.S. 132, 142-143 (1963)) or because state law stands as an impediment "to the accomplishment and execution of the full purposes and objectives of Congress" (*Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941)). See also, *e.g.*, *Capital Cities Cable, Inc.* v. *Crisp*, No. 82-1795 (June 18, 1984), slip op. 5-6. These principles apply with equal force to federal statutes and regulations alike. *Capital Cities Cable, Inc.* v. *Crisp*, slip op. 6; *Fidelity Federal Savings & Loan Ass'n* v. *de la Cuesta*, 458 U.S. at 153-154.

As this Court has repeatedly cautioned, however, preemption will not be presumed absent a clear manifestation of congressional or agency intent to supersede state legislation. See *New York Department of Social Services* v. *Dublino*, 413 U.S. 405, 413-414 (1973) (collecting cases). As the Court noted in *Dublino* (413 U.S. at 415), "[t]he subjects of modern social and regulatory legislation often by their very nature require intricate and complex responses from the Congress, but without Congress necessarily intending its enactment as the exclusive means of meeting the problem." Accord, *de Canas* v. *Bica*, 424 U.S. 351, 359 (1976). For that reason, the Court has frequently rejected preemption attacks on laws enacted pursuant to a state's police powers that paral-

leled federal law on the same subject or imposed more stringent requirements.[10] Moreover, by centralizing legislative authority in a manner inconsistent with "the presuppositions of our embracing federal system" (*de Canas* v. *Bica*, 424 U.S. at 360-361 (citation omitted)), complete preemption disables the states and localities from tailoring legislation to address local needs. Accordingly, "[p]reemption of state law by federal statute or regulation is not favored 'in the absence of persuasive reasons—either that the nature of the regulated subject matter permits no other conclusion, or that the Congress has unmistakably so ordained.'" *Chicago & N.W. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981), quoting *Florida Lime & Avocado Growers, Inc.* v. *Paul*, 373 U.S. at 142; see also *Alessi* v. *Raybestos-Manhattan, Inc.*, 451 U.S. 504, 522-523 (1981) (collecting cases).

[10] See, *e.g.*, *Pacific Gas & Electric Co.* v. *State Energy Resources Conservation & Dev. Comm'n*, 461 U.S. 190 (1983) (state statute conditioning construction of nuclear power plants on findings of economic viability by state agency not superseded by federal regulation of nuclear power plants); *Florida Lime & Avocado Growers, Inc.* v. *Paul*, *supra* (state statute prohibiting importation of avocados with oil content below a certain value not preempted by Department of Agriculture marketing order allowing interstate shipment of avocados whose maturity was measured by a different standard); *Huron Portland Cement Co.* v. *City of Detroit*, 362 U.S. 440 (1960) (city smoke abatement code sustained against claim that federal inspection laws for maritime vessels preempted such local regulation); *California* v. *Zook*, 336 U.S. 725 (1949) (state law prohibiting same conduct by motor carriers that was prohibited by federal law not preempted); *Maurer* v. *Hamilton*, 309 U.S. 598 (1940) (state statute prohibiting operation on state highways of "above the cab" carrier vehicles not preempted by Interstate Commerce Commission's licensing of such vehicles to operate interstate).

2. As the court of appeals observed (J.S. App. A11), Section 15 of Ordinance 80-12 incorporates by reference the FDA regulations governing blood plasma and plasmapheresis at 21 C.F.R. Part 640, Subpart G, as well as any future amendments to those regulations (J.S. App. A39). The Hillsborough County regulatory scheme also imposes additional licensing, donor certification, donor examination, recordkeeping, reporting, and inspection requirements, as well as fees (*id.* at A33-A42), and makes it a crime, subject to fines or imprisonment, to violate Ordinance 80-12 (J.S. App. A38). The court of appeals found that six of these additional requirements were objectionable (*id.* at A11 n.6): (1) a person may not donate plasma until he has obtained a donor registration card, at a cost of $2, which is valid for six months at a single designated plasma center; (2) before obtaining a donor registration card, a donor must receive a complete physical examination, including a test for hepatitis; he must receive a "Certificate of Good Health," as required by FDA regulations (see 21 C.F.R. 640.63(b)(3)); and he must present a sworn statement that he has not been treated for chronic or acute alcoholism during the past year;[11] (3) prior to plasmapheresis, each donor must undergo a breath analysis for alcohol content;[12] (4) each plasma center must retain and daily forward to the county health department records of each donor and plasmapheresis pro-

[11] A potential donor must also produce one of the six types of identification specified at Section 2.A of the County's regulations (see J.A. App. A40).

[12] Section 4 of the County's regulations provides that the analysis must be performed on a designated type of equipment or one of equal quality (see J.S. App. A41).

cedure performed at the center;[13] (5) the county health department is empowered to conduct at least annual inspections, without providing notice beforehand, of each plasmapheresis center; and (6) each center is taxed no more than $1 for each plasmapheresis procedure it performs in order to offset the administrative costs of the County's regulatory system.

The court of appeals ruled that these additional requirements were implicitly but completely preempted by the FDA's regulations. With one possible exception, we disagree with the court of appeals' conclusion.

B. The Public Health Service Act And The Federal Food, Drug, And Cosmetic Act Do Not Completely Preempt The County's Regulatory Scheme

The court of appeals correctly ruled (J.S. App. A7) that Ordinances 80-11 and 80-12 and their implementing Rules and Regulations are not expressly or impliedly preempted by any federal statute. Whole blood and its components, such as blood plasma, are subject to regulation by two federal statutes. The Public Health Service Act establishes licensing, labeling, and product standards for blood, blood components, including blood plasma, and blood products (42 U.S.C. 262), and the Federal Food, Drug, and Cosmetic Act, among other things, forbids the shipment in interstate or foreign commerce of adulterated or misbranded drugs (21 U.S.C. 331(a) and (b)), which includes blood components such as blood plasma. See page 2 & notes 1 & 2, *supra*.

While both statutes authorize the Secretary to regulate the interstate manufacture and sale of blood plasma, neither Act expressly forbids the states or

[13] Section 6(A) of Ordinance 80-12 also specifies certain types of information that must be included in these records (see J.S. App. A34).

local governments from adopting supplementary regulations governing the collection of blood or its components or plasmapheresis. Moreover, notwithstanding the fact that both Acts should be liberally construed in order to protect the public health (see *United States* v. *An Article of Drug* * * * *Bacto-Unidisk*, 394 U.S. 784, 798 (1969); *United States* v. *Dotterweich*, 320 U.S. 277, 284 (1943)), neither statute can reasonably be interpreted to imply the congressional intent to foreclose all supplementary state and local regulation of this narrow subject.

The legislative history of the Public Health Service Act[14] and the Federal Food, Drug, and Cosmetic

[14] The current version of 42 U.S.C. 262 traces its lineage to the Act of July 1, 1902, 42 U.S.C. (1940 ed.) 141-148, which was enacted to regulate the interstate sale and transportation of viruses, toxins, and analogous products. S. Rep. 1980, 57th Cong., 1st Sess. (1902); H.R. Rep. 2713, 57th Cong., 1st Sess. (1902); 35 Cong. Rec. 7644, 7754 (1902). Congress readopted that Act in 1944 as part of a general recodification and revision of the public health laws. The Public Health Service Act of 1944, ch. 373, § 351, 58 Stat. 702. The Public Health Service Act was thereafter amended in minor respects, not relevant here, in 1958. Act of Sept. 2, 1958, Pub. L. No. 85-881, § 2, 72 Stat. 1704. The provision in 42 U.S.C. 262 governing "blood, blood component[s] or derivative[s]" was added to Section 351 of the Public Health Service Act by Section 291 of the Heart Disease, Cancer, Stroke and Kidney Disease Amendment of 1970, Pub. L. No. 91-515, 84 Stat. 1308. Congress adopted that amendment in order to overrule the Fifth Circuit's decision in *Blank* v. *United States*, 400 F.2d at 303-305, which had held that blood components used in blood transfusions, such as blood plasma, were not biological products within the meaning of Section 351 of the Public Health Service Act. See 116 Cong. Rec. 31017 (1970) (remarks of Sen. Dominick); *ibid.* (remarks of Sen. Yarborough).

At no time throughout the history of 42 U.S.C. 262 has Congress ever suggested that supplementary state or local

Act [15] also discloses no congressional intent wholly to

---

regulation of blood, blood components or products, or plasmapheresis is completely preempted by federal law.

[15] The forerunner of the current Act was the Federal Food and Drug Act of 1906, ch. 3915, 34 Stat. 768 *et seq.* That Act, like the current version, forbade, inter alia, the sale or shipment in interstate commerce of adulterated or misbranded food or drugs. See H.R. Rep. 2118, 59th Cong., 1st Sess. 3 (1906); *United States* v. *Generix Drug Corp.*, 460 U.S. 453, 457-458 (1983); *Savage* v. *Jones*, 225 U.S. 501, 529 (1912). While the Act was designed in part to fix uniform standards for food and drugs that are shipped in interstate or foreign commerce (see, *e.g.*, H.R. Rep. 2118, *supra*, at 4-5; 40 Cong. Rec. 1417 (1906) (remarks of Sen. Heyburn)), Congress did not intend to regulate wholly-intrastate activities, but left the regulation of such local matters to the states (*ibid.*; *id.* at 2652 (Sen. Money); *id.* at 2758 (Sen. Heyburn)). Plasmapheresis, which was not mentioned during the debates on the Act (see page 17 note 16, *infra*) and which is performed on a local basis, would thus not have been preempted by that Act. Cf., *e.g.*, *Corn Products Ref. Co.* v. *Eddy*, 249 U.S. 427, 433-440 (1919) (Food and Drug Act does not preempt state law fixing labeling requirements); *Savage* v. *Jones*, 225 U.S. at 529-539 (same). Compare *McDermott* v. *Wisconsin*, 228 U.S. 115 (1913) (Food and Drug Act preempts state law making state labeling requirements exclusive).

In 1938, Congress replaced the 1906 Act with the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.* Congress amended the Act in pertinent part in the Drug Amendments of 1962 (Harris-Kefauver Act), Pub. L. No. 87-781, 76 Stat. 780 *et seq.* While the 1906 Act only forbade the introduction of adulterated or misbranded drugs into interstate commerce, the current version of the Act, as relevant here, establishes a premarketing clearance system, under which a "new drug" cannot generally be introduced into interstate commerce until the Secretary finds that it is both safe and effective for its intended use. See *United States* v. *Generix Drug Corp.*, 460 U.S. at 458; *United States* v. *Rutherford*, 442 U.S. 544, 546-548 (1979); *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 612-613 (1973). Neither that modification of the 1906 Act nor the legislative history of the

bar the states or localities from legislating in the plasmapheresis field.[16] Furthermore, the FDA does not construe these Acts to have that effect, and the agency's construction of the statutes it is entrusted to administer is entitled to substantial deference from the courts. See *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, No. 82-1005 (June 25, 1984), slip op. 6-7 & n.14 (collecting cases). Finally, the Hillsborough ordinances and regulations do not compel TPC to take any actions that are inconsistent with the requirements of either federal statute (see *Florida Lime & Avocado Growers, Inc.* v. *Paul*, 373 U.S. at 142-143), and the narrow compass of the County's measures does not interfere with the purposes of these federal Acts (see *Hines* v. *Davidowitz*, 312 U.S. at 67). Accordingly, unless the FDA's regulations governing blood and blood products provide a basis for preemption, the judgement of the court of appeals must be reversed.

1938 Act or the 1962 amendments discloses any congressional intent to preempt state or local regulation of plasmapheresis or to direct the FDA to do so. In fact, Section 202 of the 1962 amendments, 21 U.S.C. 321 note, provides that the amendments do not preempt state law absent "a direct and positive conflict" with the amendments (H.R. Conf. Rep. 2526, 87th Cong., 2d Sess. 15, 26 (1962); 108 Cong. Rec. 22040 (1962) (remarks of Sen. Kefauver)). See also *Pharmaceutical Soc'y* v. *Lefkowitz*, 586 F.2d 953, 958 (2d Cir. 1978) (state law permitting pharmacists to substitute generic for prescription drugs with attending physician's approval not preempted by Federal Food, Drug, and Cosmetic Act).

[16] That conclusion is hardly surprising. Plasmapheresis not only is performed on a local basis, but also did not become a common means of collecting blood until suitable plasma collection containers were developed during the early 1960's (see 37 Fed. Reg. 17419-17420 (1972); 2 Tr. 179).

C. The FDA's Plasmapheresis Regulations Do Not Completely Preempt The County's Regulatory Scheme

1. Two points merit discussion at the outset. First, as explained above, Congress did not itself decide whether supplementary state and local regulations should be forbidden; rather, Congress left that decision to the agency's discretion. The sole question before the Court, then, is not whether Congress intended to preempt state authority in this field, but whether the FDA intended to do so (*Capital Cities Cable, Inc.* v. *Crisp*, slip op. 6-7; *Fidelity Federal Savings & Loan Ass'n* v. *de la Cuesta*, 458 U.S. at 153-154). On that question, the FDA's construction of its own regulations is entitled to substantial deference from the courts (*Udall* v. *Tallman*, 380 U.S. 1, 16-17 (1965); *Bowles* v. *Seminole Rock & Sand Co.*, 325 U.S. 410, 413-414 (1945)). Where the construction of an agency's own regulations, rather than a statute, is at issue, " 'the ultimate criterion is the administrative interpretation, which becomes of controlling weight unless it is plainly erroneous or inconsistent with the regulation.' " *Udall* v. *Tallman*, 380 U.S. at 16-17, quoting *Bowles* v. *Seminole Rock & Sand Co.*, 325 U.S. at 413-414; accord, *United States* v. *Larionoff*, 431 U.S. 864, 872 (1977).

Here, that construction is dispositive. The FDA's blood plasma regulations, as the court of appeals acknowledged (J.S. App. A7), do not in terms preempt state or local regulation of this field. Nor can those regulations be reasonably construed to imply that intention. Indeed, the FDA made this precise point at the time it promulgated the plasmapheresis regulations.[17] In response to comments expressing

[17] These regulations, currently found at 21 C.F.R. Part 640, were originally issued in 1973 as 21 C.F.R. Part 273 and were later transferred to their current position as part of a general reorganization and recodification of the FDA's regulation of biological products (see 38 Fed. Reg. 32048 (1973)).

concern that the regulations governing the licensing of plasmapheresis facilities "would pre-empt State and local laws governing plasmapheresis" (38 Fed. Reg. 19365 (1973)), the FDA explained that (*ibid.*):

> [t]hese regulations are not intended to usurp the powers of State or local authorities to regulate plasmapheresis procedures in their localities. Rather, the intention is to assure the safety, purity, and potency of this biological product when it is shipped in interstate commerce pursuant to section 351 of the Public Health Service Act.

The FDA thus made clear that its regulations were not originally intended wholly to displace the states or municipalities from this field. While the FDA has often modified the plasmapheresis regulations since they were issued in 1973 (see, *e.g.*, 47 Fed. Reg. 30968 (1982)), the agency has not departed from its initial statement that these regulations were not intended to preempt state or local plasmapheresis regulations. Accordingly, there is no reason to construe those regulations in that fashion today.

Second, the Court ruled in *Fidelity Federal* that, when a federal agency adopts regulations that are intended to preempt state law, a reviewing court's inquiry includes the determination whether the agency's decision " 'represents a reasonable accommodation of conflicting policies' " and "is within the scope of the [agency's] delegated authority." 458 U.S. at 154, quoting *United States* v. *Shimer*, 367 U.S. 374, 383 (1961); accord, *Capital Cities Cable, Inc.* v. *Crisp*, slip op. 6. That inquiry is wholly unnecessary, however, when the agency has disclaimed any intent to preempt state law. There is no rule of administrative

law requiring a federal agency, in the absence of an express congressional directive, to preempt local authority over a particular field, and, for the reasons given above, there can be no claim that Congress has directed the FDA to preempt the exercise of local authority in the field of blood plasma (see pages 14-17, *supra*). There is also certainly no presumption in favor of complete preemption; in fact, the presumption runs the other way (see *Pacific Gas & Electric Co.* v. *State Energy Resources Conservation & Dev. Comm'n*, 461 U.S. 190, 206 (1983); *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. at 230). Hence, once a reviewing court concludes that the agency did not intend to oust the states from a particular field, no further review is necessary. For that reason, while the FDA is clearly empowered to preempt local regulations like those at issue in this case, the FDA's decision not to do so at this time cannot be challenged.

Therefore, because the FDA's statement of its intent provides a sufficient basis by itself for resolving the issue in this case, the court of appeals erred even by considering whether the FDA had impliedly preempted the County's ordinances and regulations. In any event, the reasons given by the court of appeals for concluding that the FDA had impliedly preempted the County's regulatory scheme are unsound, as we will now demonstrate.

2. The court of appeals concluded that the County's ordinances were implicitly preempted because of three factors: (a) the "comprehensive" nature of the federal regulations (J.S. App. A8-A9), (b) the "dominan[ce]" of the federal interest in the field of blood plasma regulation (*id.* at A9-A10), and (c) the court's perception that enforcement of state law would present a "serious danger of conflict" with the administration of the federal regulations (*id.* at A10-A11). Except with respect to one provision of the

ordinances and regulations, we disagree with the court of appeals' conclusion.

a. As the court of appeals itself noted (J.S. App. A9), the fact that the FDA's blood plasmapheresis regulations are broad in scope and cover most aspects of the plasmapheresis process does not alone establish that the agency intended completely to displace state or local regulatory efforts in the same area. The FDA is entrusted with the responsibility of ensuring that an adequate supply of safe, pure, and potent blood, blood components, and blood products exists to meet the nation's medical and scientific needs. In discharging that obligation, the FDA has also acted to ensure that the process for collecting and manufacturing such items does not endanger the health of donors both for their own sake and for the purpose of maintaining a healthy donor population. See, *e.g.*, 37 Fed. Reg. 17420 (1972); 38 Fed. Reg. 2965 (1973); *id.* at 19362; 39 Fed. Reg. 26161 (1974); 41 Fed. Reg. 10762-10763 (1976). The obvious complexity and technical nature of the subject matter necessarily required the FDA to adopt a comprehensive regulatory approach for this field in order to accomplish its dual goals. A detailed regulatory scheme thus "was both likely and appropriate, completely apart from any questions of preemptive intent." *Dublino*, 413 U.S. at 415; see also *de Canas* v. *Bica*, 424 U.S. at 359-360. Accordingly, while the detailed nature of a federal regulatory scheme may often provide a strong reason for inferring preemption, in this case that inference would be negated by the combination of other relevant considerations.

b. The court of appeals erred in finding that the federal interest in the area of blood plasmapheresis is so dominant as to preclude state or local laws that serve valid local interests and do not interfere with the FDA's regulatory scheme. Certainly, this field is

not one, like foreign relations, in which the national interest is so ascendant that it will necessarily displace state laws that either "complement" federal law or impose "additional or auxiliary regulations" (*Hines* v. *Davidowitz*, 312 U.S. at 66-67; see also *Zschernig* v. *Miller*, 389 U.S. 429, 440-441 (1968)) regardless of Congress's stated intent. Moreover, there is no reason at present to believe that the field of blood plasma regulation is intrinsically a subject in which national policies will inevitably be disrupted if the states and local governments also share in the effort to protect the public health.

Nor is there an express statement of congressional or agency policy that the federal interest in this field is so dominant that any additional regulations will necessarily disrupt federal goals or interests. The National Blood Policy referred to by the court of appeals (J.S. App. A9) was established in 1974 by the Department of Health, Education, and Welfare (HEW) as "a pluralistic and evolutionary approach to the solution of blood collection and distribution problems" (39 Fed. Reg. 32702 (1974)). Rather than establish a federal monopoly over this subject, the National Blood Policy was designed to stress cooperative efforts among the federal government and the public and private sectors (*id.* at 32702, 32703). Although FDA statements at the time this policy was announced recognized the significant role federal regulation was likely to play in its implementation, the policy, as originally announced, expressly stated that it was not intended to encompass the plasmapheresis area, which was to be addressed at a later date (*id.* at 32702). Nothing in this policy statement suggested that HEW or the FDA had any intention to regulate blood banking activities to the exclusion of state or local governments. The National Blood Policy, by itself, thus provides no basis for inferring complete preemption.

In ruling that the federal interest in plasmapheresis is dominant over any local interest, the court of appeals relied (J.S. App. A9-A10) upon the FDA's statement that the National Blood Policy was adopted to "assur[e] uniform adherence to the highest attainable standards of practice in blood banking, including plasmapheresis and plasma fractionation." 39 Fed. Reg. 18614 (1974); see also *id.* at 32703. The court of appeals may thus have found that the FDA's narrower interest in uniformity was dominant. If so, that conclusion interprets the federal policy too broadly. Cf. *Pacific Gas & Electric Co.* v. *State Energy Resources Conservation & Dev. Comm'n*, 461 U.S. at 205-212.

The federal government has required vendors nationwide to be subject to the same minimum product and donor safety standards to further the two-fold interest in ensuring that the national supply of safe, pure, and potent blood plasma remains adequate to meet the nation's health care needs and in protecting the health of donors for their own sake and to provide a healthy donor population. To that extent, the federal interest in plasmapheresis is dominant and the states are foreclosed from promoting a contrary policy. But neither the National Blood Policy nor the FDA's plasmapheresis regulations expresses a dominant interest in uniformity per se at the expense of supplementary state or local regulations, like those adopted by Hillsborough County, that serve legitimate public health needs and that do not adversely affect either federal interest.

The Hillsborough regulations (with one possible exception, discussed below) fall within the range of measures that the FDA has left to the states and local governments. It goes without saying that regulations protecting the public health are a legitimate exercise of the states' police power (see, *e.g.*, *Head* v.

New Mexico Bd. of Examiners in Optometry, 374 U.S. 424, 428 (1963) (statutes addressed to the protection of the public health fall "within the most traditional concept of what is compendiously known as the police power"); *Huron Portland Cement Co.* v. *City of Detroit*, 362 U.S. at 442) and that the states have the authority to regulate the various aspects of the medical profession (see, *e.g.*, *Friedman* v. *Rogers*, 440 U.S. 1, 15 (1979); *Minnesota* v. *Martinson*, 256 U.S. 41 (1921); *Dent* v. *West Virginia*, 129 U.S. 114, 121-123 (1889)). The County's concern with the health of its citizens, as expressed in Ordinance 80-12 (J.S. App. A32-A33), is thus entirely legitimate as a general matter.[18] Moreover, the measures adopted by the County to avoid these harms—the vendor licensing provisions, the donor registration process, the physical examination, breathalyzer, and affidavit requirements, and the vendors' recordkeeping and reporting obligations—not only seek to address these concerns in a rational manner, but also do not presently threaten to impede the FDA from attaining current federal goals. The incidental loss of uniformity in the standards applied to blood plasma vendors and donors nationwide, in our view, is thus unobjection-

[18] The record in this case demonstrates that the County had a rational basis for legislating in this field. As the district court found (J.S. App. A16-A17), paying plasma donors, which TPC does (*id.* at A14; 1 Tr. 34, 57), poses the risk, not present for voluntary whole blood donors, that they will donate too frequently and thereby endanger their health. Paid plasma donors, the district court also found (J.S. App. A17), have a much higher rate of hepatitis than voluntary whole blood donors. See also 39 Fed. Reg. 32703 (1974) ("voluntary donors * * * have a lower probability of "transmitting hepatitis" than commercial donors); *id.* at 32709 ("commercial donors present a relatively high risk of transmitting hepatitis", quoting HEW Task Force, *Statement of Major Findings on Blood Banking* (July 1973)).

able. See *de Canas* v. *Bica*, 424 U.S. at 360-361 (citation omitted) (preemption disfavored "'where the activity regulated [by the State] was a merely peripheral concern of the [federal regulation]'").

To be sure, blood products are widely distributed in interstate and foreign commerce. The court of appeals thus may have been correct that ensuring a safe, pure, and adequate supply of blood plasma is predominantly a federal, rather than a state or local, concern. However, state and local governments have a strong traditional interest in protecting the health of their citizens, and regulations protecting the health of blood donors and establishing safety requirements for vendors within their jurisdictions are a legitimate exercise of this authority.[19] States and localities have

[19] In the courts below, appellee claimed (see J.S. App. A16; Appellant's C.A. Br. 13-17; 1 Tr. 6; 2 Tr. 234, 247-250) that the Hillsborough County Commissioners adopted these Ordinances in response to complaints from local merchants about the presence of public inebrients and vagrants in the vicinity of TPC and that, through these Ordinances, the County intended to eliminate plasmapheresis centers by imposing severe financial burdens on their operation. That contention is unavailing, however. The Court has often noted that the quest to discover a legislature's motives for enacting a law is usually a fruitless endeavor because "[w]hat motivates one legislator to vote for a statute is not necessarily what motivates scores of others to enact it" (*Pacific Gas & Electric Co.* v. *State Energy Resources Conservation & Dev. Comm'n*, 461 U.S. at 216; see also *Michael M.* v. *Superior Court*, 450 U.S. 464, 469-470 (1981) (plurality opinion); *United States* v. *O'Brien*, 391 U.S. 367, 383-384 (1968)). What is more, that inquiry is "particularly pointless" under the Supremacy Clause (*Pacific Gas & Electric Co.*, 461 U.S. at 216). Just as a local legislature may not frustrate federal law simply by adopting an ordinance with some other purpose in mind (*Perez* v. *Campbell*, 402 U.S. 637, 651-652 (1971)), so too an ordinance that does not otherwise conflict with federal statutes or policies is not preempted even if the local legislature intended to be obstructive (*Pacific*

also historically shared with the federal government an interest and an active role in assuring a safe and adequate supply of blood. For example, many federally licensed blood banks are concurrently licensed by states in which they are located. See 39 Fed. Reg. 32710, Table 1 (1974); 37 Fed. Reg. 17419 (1972). Accordingly, we are not prepared to say that at this time the federal government's interest in regulating blood and plasma products is so dominant that it precludes enforcement of state laws that are consistent with the federal regulatory scheme.

c. It follows that Hillsborough's ordinances and regulations are not preempted unless it is impossible to comply with them without violating the FDA's regulations or without frustrating the objectives of the federal regulatory program. Here, compliance with both federal and state regulations is not "a physical impossibility." *Florida Lime & Avocado Growers, Inc.* v. *Paul*, 373 U.S. at 142-143. Indeed, the Hillsborough ordinances expressly incorporate the FDA's plasmapheresis regulations, and, with one possible exception, nothing in the ordinances or implementing regulations requires actions that would violate the federal rules. For instance, the federal regulations do not forbid local governments from adopting a donor identification card requirement, like the one at Sections 4 and 5 of Ordinance 80-12, which is

Gas & Electric Co., 461 U.S. at 216). In either case, what counts is the effect of the ordinance upon federal laws or policies, not the legislators' motives for adopting the ordinance.

It also deserves mention that the County has a legitimate interest in preventing alcoholics from jeopardizing their health by excessively selling their blood plasma or by submitting to plasmapheresis without appreciating the consequences of doing so. In fact, the district court found that the health risks resulting from excessive donations of blood plasma (J.S. App. A16) are particularly acute for chronic alcoholics suffering from liver malfunction (*ibid.*).

designed to ensure that persons do not donate plasma at more than one plasmapheresis center within the time period set by the FDA. The FDA's regulations require each plasmapheresis center to obtain the donor's informed consent prior to undergoing plasmapheresis (21 C.F.R. 640.61), but those rules do not forbid a local government from requiring a potential donor to pass a breath analysis for alcohol content as part of obtaining his informed consent, as Section 7 of Ordinance 80-12 requires. The Hillsborough regulatory scheme also provides for local inspections of plasmapheresis facilities, but does not impose any health or safety requirements that are inconsistent with federal law.[20] And the FDA's regulations also offer no immunity from the fees imposed by the County upon commercial blood plasma donors and vendors.

With one possible exception, it also does not appear at this time that the Hillsborough ordinances and regulations "stand[] as an obstacle to the accomplishment * * * of the full purposes and objectives of [the FDA]." *Hines* v. *Davidowitz*, 312 U.S. at 67. The Hillsborough provisions requiring local licensing, certification of donors, recordkeeping, reporting, and inspection are more stringent than, but are not inconsistent with, the federal regulations. The court of appeals found (J.S. App. A11) that these provisions are "burdensome and expensive" and that they threaten "the national blood policy of promoting uniformity and guaranteeing a continued supply of healthy donors." Overly restrictive local legislation

[20] Appellee claims (Mot. to Aff. 14) that the inspection provisions of the County's scheme threaten to subject TPC to local requirements that are inconsistent with those imposed by the FDA. That risk is speculative at present, however, because the current version of the County's ordinances and regulations do not themselves have that effect.

could threaten the national plasma supply, and the cumulative effect of widespread adoption of regulations like those at issue here could, by raising the cost to firms like TPC of supplying blood plasma for interstate or foreign commerce, also lead to that result. But at this time the FDA has not identified such a threat.[21] Should a threat someday become apparent, the FDA possesses the authority to issue regulations preempting such local legislation. However, the FDA does not presently foresee that local ordinances like Hillsborough's will have the effect that the court of appeals envisioned.

As previously noted, the primary objectives of the FDA's plasmapheresis regulations are to ensure that plasma can be collected in such a way as to assure the safety, purity, and potency of the final products to be manufactured from it, as well as to protect plasmapheresis donors. See 39 Fed. Reg. 26161 (1974). The agency believes that its standards, if complied with, are fully adequate to achieve both goals. Nonetheless, with the limited exception noted below, the Hillsborough ordinances in question are not inconsistent with the dual federal goals of assuring product and donor safety and maintaining an adequate national supply of blood. Under these circumstances, the court of appeals erred by finding complete preemption in this case.

---

[21] Nor is there any basis in this record for the court of appeals' conclusion. With the exception of the breathalyzer requirement, the district court found (J.S. App. A15, A18) that appellee's claims of burden and added expense in complying with the ordinances were speculative and that there was no factual basis in the record for appellee's claim that the donor population would decrease significantly if the ordinances were enforced. The court of appeals did not rule that these findings were clearly erroneous (see *Pullman-Standard* v. *Swint*, 456 U.S. 273 (1982)); nor did the court identify any basis for such a ruling.

II. THE FDA'S REGULATIONS MAY PARTIALLY PREEMPT THE COUNTY PROVISIONS THAT FORBID CERTAIN DONORS FROM UNDERGOING PLASMAPHERESIS UNLESS THEY HAVE FIRST OBTAINED A CERTIFICATE OF GOOD HEALTH

In one respect, the County's ordinances and regulations may conflict with federal regulations. By virtue of Section 6(D) of Ordinance 80-12 and Section 2.B of the implementing Rules and Regulations (J.S. App. A35, A40), plasma donors are in every case prohibited from receiving a donor registration card necessary to undergo plasmapheresis until an examining physician issues a "Certificate of Good Health as required by [21 C.F.R. 640.63(b)(3)]." Under 21 C.F.R. 640.75, however, the FDA may authorize specific plasmapheresis facilities to collect blood from donors who have tested positive for hepatitis B surface antigen or have other conditions that render them, by any reasonable medical description, not in "good health," as required by 21 C.F.R. 640.63(c).

If the Hillsborough measures apply to plasmapheresis centers that hold such an exemption from the FDA, those measures would expressly conflict with the FDA's regulations in this respect and would thus be invalid. See *Capital Cities Cable, Inc.* v. *Crisp*, slip op. 12-16. Moreover, the Hillsborough provisions would also directly prevent private plasmapheresis centers from carrying out a valuable federal policy in this respect. The collection of plasma from individuals with hepatitis, under carefully controlled conditions, is necessary to produce the vaccine used to prevent hepatitis (21 C.F.R. 610.41), as well as the diagnostic products used to identify the presence of disease. The Hillsborough provisions, by interfering with the ability of private plasma vendors and donors to contribute towards the amelioration of disease, would "stand[] as an obstacle to the accomplishment

and execution of the full purposes and objectives of the [FDA]" (*Hines* v. *Davidowitz*, 312 U.S. at 67). Accordingly, Hillsborough's ordinances and regulations would be preempted to the extent that they preclude donors who are or have been hepatitis-reactive or who are otherwise not in good health from donating plasma in a manner consistent with specific exemptions granted by the FDA under 21 C.F.R. 640.75. See also *Capital Cities Cable, Inc.* v. *Crisp*, slip op. 7-16.

There are two reasons, however, why it may be unnecessary for the Court to decide that question in this case. First, appellee appears to lack standing to raise this specific claim. To our knowledge, the complaint does not allege that either appellee AML or TPC currently holds an exemption under 21 C.F.R. 640.75. Thus, appellee cannot contend that the Hillsborough ordinances and regulations prevent it from engaging in conduct expressly authorized by federal law. Second, while the matter is not entirely clear,[22] the County's provisions may incorporate the exemptions granted to specific plasmapheresis centers by the FDA. If so, preemption would be inappropriate.

---

[22] Section 6(D) of Ordinance 80-12 and Section 2.B of the implementing Rules and Regulations in terms forbid a person from undergoing plasmapheresis until he has received the certificate that these provisions require. However, the state courts may be able to reconcile these portions of the County's regulatory scheme with the FDA's regulations (see, *e.g.*, *de Canas* v. *Bica*, 424 U.S. at 357 n.5). Otherwise, if the County intended to incorporate all of the FDA's regulations, including the exemption provisions, the County can easily issue a new regulation making clear that the FDA's exemption process is also incorporated into the local regulatory scheme.

CONCLUSION

With the reservations stated in Point II of this brief, the judgment of the court of appeals should be reversed and the case remanded to that court for further proceedings to resolve the issues that were not addressed by the court of appeals.

Respectfully submitted.

REX E. LEE
Solicitor General

RICHARD K. WILLARD
Acting Assistant Attorney General

KENNETH S. GELLER
Deputy Solicitor General

PAUL J. LARKIN, JR.
Assistant to the Solicitor General

MARGARET E. CLARK
IRENE M. SOLET
Attorneys

FEBRUARY 1985

☆ U. S. GOVERNMENT PRINTING OFFICE: 1985 481831 10180

IN THE

Supreme Court of the United States

October Term 1984

No. 83-1925

HILLSBOROUGH COUNTY, FLORIDA, et al.,
Appellants

v.

AUTOMATED MEDICAL LABORATORIES, INC.,
Appellees

On appeal from the
UNITED STATES COURT OF APPEALS
for the Eleventh Circuit

BRIEF AMICUS CURIAE OF THE AMERICAN BLOOD COMMISSION IN SUPPORT OF THE DECISION OF THE COURT OF APPEALS.

Michael H. Cardozo
Suite 1004, 1001 Connecticut Ave., N.W.
Washington, D.C. 20036
(202) 872-1401
Attorney for Amicus Curiae, American Blood Commission

Table of Contents

Table of Authorities

IN THE

Supreme Court of the United States

OCTOBER TERM 1984

No. 83-1925

Hillsborough County, Florida, et al.,
Apellants

v.

Automated Medical Laboratories, Inc.,
Appellee

On Appeal from the United States
Court of Appeals for the Eleventh Circuit

BRIEF AMICUS CURIAE OF THE AMERICAN BLOOD COMMISSION IN SUPPORT OF THE DECISION OF THE COURT OF APPEALS.

The American Blood Commission has received written consent of the Appellant and the Appellee for the filing of this amicus brief.

INTEREST OF AMICUS

The American Blood Commission is a non-governmental organization established to help assure all the people of the nation of a safe and adequate supply of blood and blood components.

The Commission was created in 1975 at the invitation of the Secretary of Health, Education and Welfare, issued to organizations in the private sector concerned with blood services and the uses of blood and its derivatives. The mission of the American Blood Commission was to implement the National Blood Policy promulgated by the secretary in the private sector.

The members of the Commission include organizations that collect and distribute over ninety percent of the blood and blood components used in transfusions and some of the plasma required for the nation's health care; they also include organizations representing blood donors and users of blood products. A list of the members appears in the body of this brief.

The members of the Court are fully aware that human blood, its components and its derivatives are now an essential element in health care. In addition, no artificial substitute for it exists. Consequently any threat to the system of distribution of blood products throughout the nation is of major national importance and a direct concern not only to the members of the American Blood Commission, but also to the donors and the recipients of blood and blood products.

Ordinances and regulations of the type promulgated by Hillsborough County in Florida and involved in this case could seriously interfere with the availability of blood and its components collected and distributed under the current system of sharing blood resources developed by the private sector organizations. That system involves, under mandate of Congress, the strict regulation and licensing of blood services facilities by United States Government agencies, whether

the facilities are not-for-profit or commercial, and whether they produce red cells and derivatives, or only plasma and its derivatives.

By virtue of the uniform federal system of control over donations, processing and storing, demands from all parts of the country are being filled without fear of contamination through improper procedures required by local governmental units. The Hillsborough County ordinances and regulations are just such potentially damaging measures. Consequently the American Blood Commission files a brief amicus curiae to explain how measures of that kind (a) can do harm to the blood service system of the nation; (b) can impose a serious burden on the movement of a vital product in interstate commerce; and (c) consequently, under the Supremacy Clause of Article VI of the Constitution, are impermissible invasions of an area of regulation preempted by Congress.

STATEMENT

The appellee in this case operates commercial centers for the production of plasma by plasmapheresis. Plasma is the fluid portion of blood that carries all the components of blood to every part of the body. When whole blood is extracted in a donor center, it contains red blood cells and plasma, which together include all the elements that compose the unique substance called "blood." The red blood cells are readily separated from plasma after blood has been drawn from a donor's veins. In the pheresis process, the red blood cells are returned to the donor, and the plasma is further processed into products for transfusior and other health uses.

All aspects of the collection of blood and its derivatives are subject to control by comprehensive federal statutes and regulations to assure safety of donors at the start of the process and to patients receiving these transfusions

to improve their health status. 42 U.S. Code, Sec. 262. In 1980, Hillsborough County adopted several ordinances adding requirements in the plasmapheresis process when operated by commercial organizations. Most, but not all, of the plasma collected and processed in the United States is produced by commercial organizations similar to those operated by appellee.

The appellee brought an action in U.S. District Court for the Middle District of Florida for a declaration of invalidity of the Hillsborough ordinances on the ground of incompatibility with the preempting federal regulatory system, and therefore invalid under the Supremacy Clause of Article VI of the Constitution. The District Court found one part of the ordinances inconsistent with the Constitution but upheld the balance. The Court of Appeals affirmed as to the holding of invalidity, but reversed as to the balance of the ordinances, stating that all the

ordinances were preempted by the federal scheme of regulation, which would be "adversely affected" by the County measures. (722 F. 2d 1526 (1984.))

The County appealed, and this Court noted probable jurisdiction on January 14, 1985.

SUMMARY OF ARGUMENT

The successful operation of a pluralistic national system of collection and distribution of a safe and adequate supply of blood and blood products depends on a continuous flow of donations by individuals motivated by a public interest in supporting the health care of fellow citizens. Anything that jeopardizes the effective operation of that system jeopardizes the life and welfare of every patient needing transfusion of blood or a blood product. The United States Congress has, by statute supported by regulation, provided for comprehensive licensing, inspection and testing of blood

services. The scope of the federal government regime of regulation evidences its intention to occupy the field. Any state or local statute or regulation that adds to or subtracts from that regime, or otherwise threatens to obstruct or interfere with it, is preempted and is invalid under the Supremacy Clause of Article VI of the Constitution. The Hillsborough County ordinances threaten that obstruction and interference and therefore were properly held invalid by the Court of Appeals.

ARGUMENT

The American Blood Commission presents this brief as amicus curiae because of its conviction that the uncoordinated intervention of state and other governmental units, besides the federal government, in the regulation of the blood service system could seriously interfere with and do damage to the nationwide availability and distribution of a unique

product that is essential in our health care system. The Commission supports the holding of the Court of Appeals that the Constitution protects the people of the nation from the harm that could result from local action in an area that is national in scope and that has been subject to comprehensive regulation by authority of Congress.

THE AMERICAN BLOOD COMMISSION AND THE NATIONAL BLOOD POLICY

The American Blood Commission is a non-governmental organization established to help assure all the people of the nation of a safe and adequate supply of blood and blood components. The Commission was created in 1975 at the invitation of the Secretary of Health, Education and Welfare, issued to organizations in the private sector concerned with blood services and the uses of blood, its components and derivatives. In 1973 the Secretary of Health, Education and Welfare announced a "National

Blood Policy," calling for "a pluralistic and evolutionary approach to the solution of blood collection and distribution problems." (Federal Register, Vol. 39, September 10, 1974, page 32703.)

In 1974, the Secretary approved a plan for the establishment of an American Blood Commission and announced the Department's intention to cooperate with the Commission in implementing the National Blood Policy. (39 F.R. 32707, Sept. 10, 1974). The Commission was formally established in 1975 and has carried out this mandate for ten years. A historical summary of the American Blood Commission was published in the October, 1978 issue of Lab World, page 22. The present membership of the Commission consists of the following national, not-for-profit organizations:

American Association for Histocompatibility and Immunogenetics
American Association of Blood Banks
American Association of Donor Recruitment Professionals
American Association of Retired Persons
American Association of Tissue Banks

American College of Physicians
American College of Surgeons
American Federation of Labor-Congress of Industrial Organizations
American Heart Association
American Hospital Association
American Legion
American Medical Association
American Nurses' Association
American Osteopathic Association
American Red Cross
American Society for Apheresis
American Society of Anesthesiologists
American Society of Clinical Pathologists
American Society of Hematology
Blue Cross/Blue Shield Association
College of American Pathologists
Communications Workers of America
Cooley's Anemia Foundation
Council of Community Blood Centers
Health Insurance Association of America
Leukemia Society of America
National Association for Sickle Cell Disease, Inc.
National Association of Patients on Hemodialysis and Transplantation, Inc.
National Kidney Foundation
Pharmaceutical Manufacturers Association
The National Hemophilia Foundation
United Way of America
Veterans Administration

THE NATURE OF BLOOD SERVICES

Blood is a unique substance, and the blood services industry is a unique feature of human society. Because science has not developed an artificial substitute for blood, only one source exists: the human veins and arteries through which flows this essential

"river of life." To fill the needs of operating rooms throughout the nation and in every home of a hemophiliac patient, a parade of individual donors must continuously donate their units of blood in every part of the country. An accident or other emergency on the west coast may create an immediate need for types of blood available only on the east coast. The doctors, the hospitals and the patients must have full confidence that the blood bags sent by jet transport contain safe, healthful blood of the required type. The need is national in scope; the assurance must have a national imprimatur.

The system of collection and delivery of blood and its components calls for a special alliance between the individuals who voluntarily offer their veins for the drawing of blood and the institutions that provide the services of the system. Some of those institutions collect, prepare and distribute the blood and its products; others prescribe

the measures that provide its purity and safety; and finally the hospitals and doctors deal with the direct needs of patients. Thus is formed the chain that now provides this essential element in the nation's health care. The National Blood Policy reflects offical recognition of the importance of this alliance among individual donors, private organizations and government agencies. Anything that threatens the alliance and its mechanism is a threat to health care everywhere in the nation.

THE THREAT FROM LOCAL REGULATION

The federal government has promulgated, by statute and regulation, comprehensive rules concerning the blood service system of the nation. The scope of those rules is demonstrated by the embracing language of the authorizing statutory provisions, found in the Appendix of this brief.

These enactments of the federal government,

by their very words, evidence the Congressional intent to "occupy the field" of assuring the safety of the nation's blood services. No express statement of that intention is needed: "Even if Congress has not expressly preeempted state law in a given area, a state statute may nevertheless be invalid under the Supremacy Clause if it conflicts with federal law or 'stands as an obstacle to the accomplishment of the full purposes and objectives of Congress'." Lawrence County v. Lead-Deadwood School District, decided January 9, 1985, 105 S.Ct. 695, 698, quoting from Silkwood v. Kerr-McGee Corporation, decided January 11, 1984, 104 S.Ct. 615. In many ways, regulation of blood services by governmental units and agencies other than the federal government can create conflicts and obstacles in the effective operation of the blood service system envisioned in the National Blood Policy. The Court of Appeals in the present case found that the Hillsborough County ordinances impose "burdensome and

expensive requirements" beyond the "comprehensive federal scheme" in one essential element in that system, and that it would consequently be "adversely affected." If the analysis by the Court of Appeals is correct, the ordinances could not survive the command of the Supremacy Clause.

THE COUNTY ORDINANCES

The Hillsborough County ordinances involved in this case are addressed only to the collection of plasma from donors.

Plasma is "the fluid that is contained within the cardiovascular system"; it provides the carrier or "medium of exchange" of the numerous minerals and other substances that circulate through the body. Plasma is readily separated from the red cells and each part is processed separately. A large proportion of the plasma and plasma derivatives is collected, processed and distributed through commercial blood banks and pharmaceutical concerns.

Most of the red cells and their components, on the other hand, are collected, processed and distributed for transfusions in a not-for-profit context, starting with donors who receive no pay for their donations and passing through a non-commercial system to their ultimate destination in the operating rooms.

The members of the American Blood Commission are all not-for-profit organizations. Only a relatively small part of the products that pass through their hands is plasma. Nonethless, the outcome of this case is of great concern to them. If local governmental units, by their effort to regulate health services, can interfere with the collection and distribution of one blood product, such as plasma, by commercial organizations, they can also impede the delivery of a safe and adequate blood supply donated voluntarily for patient use. This is why the Commission has entered the present case.

The Hillsborough County ordinances will

potentially cause harm to the blood service system in several ways. They are adequately described in the opinion of the Court of Appeals and in the briefs filed on behalf of the Medical Laboratory and the American Blood Resources Association. A description of one threatening provision should suffice in this amicus brief.

Ordinance 80-12 first cites the federal regulations applicable to plasma. Then the Ordinance adds several requirements for donors of plasma through the "plasmapheresis" process. The Ordinance requires the following procedures over and above the requirements of the federal regulations:

1. Every donor must obtain from County authorities a "donor registration card" that will be valid for six months;

2. The donor registration card will be issued only after a complete physical examination and a hepatitis test;

3. Reports on a daily basis to the

County Health Department;

4. Breathanalysis of each donor immediately prior to donation; and

5. Payment to the County of $1.00 for each application of phasmapheresis.

These requirements create conflict with the federal system by requiring a donor ID card every six months, by requiring a complete physical examination of the donor before donating, instead of testing the drawn blood for Hepatitis B - "surface antigen" as required by the federal regulations, and by exacting a fee of $1.00 for each donation. All of these requirements obviously could create complications incident to the collection of plasma.

If local ordinances, statutes or regulations begin to appear in many parts of the country, the situation could become extremely damaging. Already, for example, the California legislature is considering a bill imposing restrictions on blood donating and banking that on its face would conflict with the system of regulations

f the federal government. Assembly Bill No. 88, California Legislature 1985-86, Regular ession.

Anything that causes public hesitancy to ontribute blood and blood products of any ind is dangerous, and today it has become oubly harmful. The widely publicized development f a new disease, AIDS (Acquired Immune eficiency Syndrome) and its suspected connection ith blood and derivatives, has contributed o public fears about blood donations. lthough experts consider those fears are nwarranted, they threaten the delicate tie f individual donors to the system of voluntary onations that underlies the National Blood olicy. Consequently, the national interest equires the avoidance of any obstacle to lood donations that is not needed for the rotection of public health. Since the ederal government has determined the full easure of what is needed for that purpose, he interference of the County Ordinances annot be allowed to invade the domain

preempted by acts of Congress.

THE LAW OF PREEMPTION

Long history supports the principle that the Supremacy Clause of Article VI of the Constitution disables states and local units from intruding with inconsistent actions where the federal government has acted. The principle has been summarized and supported with precedents of this Court in terse sentences in Professor Laurence Tribe's "American Constitutional Law":

> " . . . state action may . . . be struck down if it is in 'actual conflict' with the objectives that underlie federal enactments (page 378.) . . . the Court will now sanction state regulations that supplement federal efforts so long as compliance with the letter or effectuation of the purpose of the federal enactment is not likely to be impeded by the state law. (page 379) . . . where a multiplicity of federal regulations govern a given field, the pervasiveness of the regulations will help to sustain a conclusion that Congress intended to

exercise exclusive control over the subject matter. (page 385)" [1]

An indication of the Congressional intention to preempt the field of blood services appears in the section of the Code following the section which deals with blood. That following section (§263) deals with laboratory examination of human materials. In subsections (k) and (l), it states that certain regulations of the states "not inconsistent with the provisions of this section" are not affected by the federal regulations, or may be exempted by the Secretary. No such provisions were attached to the provisions regulating blood donations, processing and distribution on a national basis. Congress intended to keep those functions exclusively in federal hands.

1. The authorities cited by Professor Tribe for these statements are: Page 378: Nash v. Florida Industrial Commission, 389 U.S. 235, 239 (1967); page 379: Amalgamated Association of Street Electric Railway & Motor Coach Employees of America v. Lockridge, 403 U.S. 274, 296 (1971); Castle v. Hayes Freight Lines, 348 U.S. 61 (1954).

This summary of the principles of federal preemption fully supports the conclusion of the Court of Appeals that the federal purposes are impeded by the Hillsborough County ordinances and that the ordinances cannot survive the force of the Supremacy Clause. This conclusion applies despite the fact that the ordinances apply in the field of public health, an area often seen as peculiarly within the police power of the states. The Court has held that even "in a field which the states have traditionally occupied," their powers may be superseded by federal action if "that was the clear and manifest purpose of Congress." Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947). The "clear and manifest purpose of Congress" in enacting the regulations governing blood services, and of the executive Department of HEW in promulgating the National Blood Policy in implementation of the statutory scheme, was to assure a national, uniform, uninterrupted flow of safe blood and blood

products. The County ordinances are manifestly inconsistent with that purpose. Therefore, the decision of the Court of Appeals holding them invalid should be affirmed.

Conclusion

The amicus curiae respectfully requests the Court to affirm the decision of the Court of Appeals for the Eleventh Circuit in favor of the Appellees.

Respectfully submitted,

Michael H. Cardozo
Suite 1004, 1001 Connecticut Ave., N.W.
Washington, D.C. 20036
(202) 872-1401
Attorney for Amicus Curiae, American Blood Commission

Appendix

TITLE 42-THE PUBLIC HEALTH AND WELFARE

PART F-LICENSING OF BIOLOGICAL PRODUCTS AND CLINICAL LABORATORIES AND CONTROL OF RADIATION

SUBPART 1-BIOLOGICAL PRODUCTS

§262. Regulation of biological products

(a) Intrastate and interstate traffic; suspension or revocation of license as affecting prior sales

No person shall sell, barter, or exchange, or offer for sale, barter, or exchange in the District of Columbia, or send, carry, or bring for sale, barter, or exchange into any other State or possession into any foreign country, or from any foreign country into any State or Possession, any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood components or derivative, allergenic product, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of diseases or injuries of man, unless (1) such virus, serum, toxin antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product has been propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license, issued by the Secretary as hereinafter authorized, to propagate or manufacture, and prepare such virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product for sale in the District of Columbia, or for sending, bringing, or carrying from place to place aforesaid;

and (2) each package of such virus, serum, toxin, antitoxin, vaccine, blood, blood component, or derivative, allergenic product, or other product is plainly marked with the proper name of the article contained therein, the name address, and license number of the manufacturer, and the date beyond which the contents cannot be expected beyond reasonable doubt to yield their specific results.

(c) Inspection of establishment for propagation and preparation

Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried or brought from any State or Posession into any other State or Possession or into any foreign country, or from any foreign country into any State or Possession.

(d) Regulations governing licenses

Licenses for the maintenance of establishments for the propagation or manufacture and preparation of products described in subsection (a) of this section may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards. All such licenses shall be issued, suspended, and revoked as prescribed by regulations and all licenses issued for the maintenance of establishments for the propagation or manufacture and preparation, in any foreign country, of any such products for sale, barter, or exchange in any State or possession shall be issued upon condition that the licensees will permit the inspection of their establishments in accordance with subsection (c) of this section.

No. 83-1925

in the

Supreme Court

of the

United States

OCTOBER TERM, 1984

HILLSBOROUGH COUNTY, FLORIDA AND
HILLSBOROUGH COUNTY HEALTH DEPARTMENT
Appellants,

v.

AUTOMATED MEDICAL LABORATORIES, INC.,
Appellee.

APPELLEE'S BRIEF ON THE MERITS

LARRY A. STUMPF
Counsel of Record
VICTORIA L. BADEN
Members, United States
Supreme Court Bar

FINLEY, KUMBLE, WAGNER,
HEINE, UNDERBERG, MANLEY
& CASEY
Counsel for Appellee
Suite 1000, Flagship Center
777 Brickell Avenue
Miami, Florida 33131
(305) 371-2600

CHARLES F. JOHNS,
On the Brief

QUESTIONS PRESENTED

A. Where the federal legislation and attendant regulation in a given field is pervasive, what is the proper test to be applied in determining whether local legislation in the same field is pre-empted?

B. Does application of the appropriate test for pre-emption mandate a holding that the subject Hillsborough County ordinances regulating the plasmapheresis procedure are pre-empted by federal regulation of the plasmapheresis procedure under the Public Health Service Act?

TABLE OF CONTENTS

TABLE OF CONTENTS (continued)

TABLE OF CONTENTS (continued)

TABLE OF AUTHORITIES

NO. 83-1925

in the

Supreme Court

of the

United States

OCTOBER TERM, 1984

HILLSBOROUGH COUNTY, FLORIDA AND
HILLSBOROUGH COUNTY HEALTH DEPARTMENT
Appellants,

vs.

AUTOMATED MEDICAL LABORATORIES, INC.,
Appellee,

APPELLEE'S BRIEF ON THE MERITS

OPINIONS AND JUDGMENTS BELOW

The opinion (JA 40-46)[1] and final judgment (JA 47) of the United States District Court for the Middle

[1]References to the Joint Appendix are indicated by (JA), the Jurisdictional Statement Appendix by (JSA), and the Transcript by (TR).

District of Florida, William J. Castagna, J., are not reported. The opinion (JA 48-59) of the United States Court of Appeals for the Eleventh Circuit is reported at 722 F.2d 1526. The final judgment (JA 60) is not reported.

JURISDICTION

The judgment of the Court of Appeals was entered on January 16, 1984 (JSA 21). A petition for rehearing by panel was denied on February 23, 1984 (JSA 22-26) and a notice of appeal was filed on April 20, 1984 (JSA 27). This Court noted probable jurisdiction on January 14, 1985. The jurisdiction of this Court rests upon 28 U.S.C. §1254(2).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

1. This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding. United States Constitution, Article VI, clause 2.

2. Public Health Service Act, Sections 351 & 361, 42 U.S.C. §§262 & 264.

3. Federal Food, Drug and Cosmetic Act, 21 U.S.C. §321, *et. seq.*

4. 21 C.F.R. §600.3-680.26 (1983).

5. Hillsborough County Ordinances 80-11 and 80-12 and the rules and regulations promulgated thereunder (JA 21-34).

STATEMENT OF THE CASE

On November 26, 1980, Appellant, HILLSBOROUGH COUNTY, FLORIDA ("County"), adopted Ordinances 80-11 and 80-12 (JA 21-31), purporting to regulate plasmapheresis establishments and the eligibility of donors of blood plasma.[2] Ordinance 80-11 (JA 21-23) imposed a license tax on blood plasma centers, and required licensees, among other things, to permit inspection of blood plasma centers by Appellant HILLSBOROUGH COUNTY HEALTH DEPARTMENT ("Department"). Ordinance 80-11, in addition, required blood plasma centers located within Hillsborough County to provide continuously updated information to the Department regarding their ownership, employees, equipment and facilities.

Ordinance 80-12 (JA 24-31), and the rules and regulations promulgated thereunder (JA 32-34), required that a blood plasma donor, prior to donating plasma, undergo a medical examination and obtain a certificate of good health, and to obtain from the Department an identification card, which identification card would have

[2]Plasmapheresis is a process whereby, during a single procedure, blood is removed from a human donor, the plasma is removed from the whole blood, and the red blood cells are returned to the donor (JA 50; 722 F.2d at 1527-1528; *see also*, 21 C.F.R. §606.3(e)).

permitted the potential donor to undergo plasmapheresis for a period of six months only, and only at a single specified plasma center within Hillsborough County. Ordinance 80-12 also required licensee plasma centers to submit to the Department, on a daily basis, and as to each procedure performed, detailed information regarding the donor, reports of testing, and results of the procedure. Ordinance 80-12 also required licensee plasma centers to pay to the Department a fee of $1.00 for each procedure performed.

Appellee, AUTOMATED MEDICAL LABORATORIES, INC. ("AML"), a Florida corporation which, through a wholly owned subsidiary corporation known as Tampa Plasma Center, operates a blood plasma center in Tampa, Hillsborough County, Florida, filed a civil action against the County and the Department in the United States District Court for the Middle District of Florida, challenging the constitutionality of the Ordinances (JA 5-34). AML's complaint challenged the County regulatory scheme on the grounds that it was pre-empted by regulations of the United States Food and Drug Administration ("FDA") (21 C.F.R. Subchapter F-Biologics), that it imposed an undue burden on interstate commerce, that it denied AML its right to equal protection of the law, and for other reasons.

After a non-jury trial, the United States District Court for the Middle District of Florida entered its opinion (JA 40-46) and final judgment (JA 47), on November 1, 1982, holding §7 of Ordinance 80-12 and §4 of the rules and regulations (dealing with required breathalyzer tests) unconstitutional, as impermissibly burdening interstate commerce, and upholding the remainder of the County regulatory scheme.

AML appealed to the United States Court of Appeals for the Eleventh Circuit, and the County cross-appealed with respect to the portions of the Ordinances invalidated by the District Court.

The Eleventh Circuit held that Ordinances 80-11 and 80-12 were invalid, because the County regulatory scheme was wholly pre-empted by federal regulation of the area, under the tests enunciated in *Pennsylvania v. Nelson*, 350 U.S. 497, 76 S.Ct. 477 (1956) (JA 48-59; 722 F.2d 1526 (1984)). Accordingly, the Eleventh Circuit did not decide the other questions raised on the appeal.

Hillsborough County petitioned for rehearing by panel (JSA 22-25). In its petition, the County explicated its view that the Eleventh Circuit had erred in holding that federal law pre-empted its Ordinances, had ignored record evidence and had misapplied the law. The Eleventh Circuit denied the petition for rehearing (JSA 26).

SUMMARY OF ARGUMENT

Pursuant to the Supremacy Clause of the United States Constitution, the laws of the United States are "the supreme Law of the Land." Accordingly, local legislation that interferes with, or is contrary to, federal law is invalid under the doctrine of federal pre-emption.

In interpreting and applying the Supremacy Clause, and in establishing and defining the doctrine of federal pre-emption, this Court consistently has held that where Congress intends, either expressly or impliedly, that a federal regulatory system covering an area of permissible federal regulation is the exclusive regulatory system, local legislation in that area is pre-empted.

It is equally well-settled that, when promulgated with appropriate legislative authority, federal regulations have pre-emptive effect equal to that of federal statutes.

The first step, then, in a proper pre-emption analysis is an examination of the statutory and regulatory framework. In the case at bar, the system of federal regulation of the plasmapheresis industry is grounded upon the Public Health Service Act, 42 U.S.C. §262, *et seq.* (and, to a much lesser degree, upon the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §321, *et seq.*).[3]

The relevant portions of the Public Health Service Act provide that no person shall sell any blood component or derivative (including blood plasma collected by plasmapheresis) unless the product was propagated or manufactured at an establishment holding a valid license from the Food and Drug Administration ("FDA"). Licenses for plasmapheresis establishments are, in turn, granted pursuant to extensive FDA regulations promulgated to ensure the safety and purity of blood components, to ensure the safety of the (paid) donors of plasma who undergo the plasmapheresis procedure, and to ensure the continued adequate supply of plasma, collected by the plasmapheresis procedure and subsequently manufactured into vitally important pharmaceutical products.

Acting pursuant to the statutory authority of Section 361 of the Public Health Service Act, the FDA has

[3]The statutory framework for the federal regulation of the plasmapheresis industry is described at pages 1-4 of the Brief for the United States, as *Amicus Curiae*. AML finds that description to be accurate.

promulgated comprehensive regulations,[4] found by the United States Court of Appeals for the Eleventh Circuit in this case to be pervasive, to be broad in scope and to "cover virtually every phase of the plasmapheresis process" (JA 56; 722 F.2d at 1531). There is no dispute among the parties as to the comprehensiveness of the regulations.

In its analysis of the doctrine of federal pre-emption as applied to the facts of the case at bar, the Eleventh Circuit carefully considered the correct, well-settled and recently restated principles of pre-emption analysis. The Eleventh Circuit concluded that, while the statutes and regulations involved do not expressly pre-empt local legislation, the federal system of regulation has, by implication, pre-empted local legislation.

More specifically, the Eleventh Circuit carefully applied the tests for determining the issue of implied pre-emption, as articulated in *Pennsylvania v. Nelson*, 350 U.S. 497, 76 S.Ct. 477 (1956), and concluded that (i) the federal regulations are comprehensive and fill the entire field of regulation, (ii) the federal law concerns a field of dominant federal interest and (iii) enforcement of the County legislation would present a serious danger of conflict with the administration of the federal system. (JA 55-59; 722 F.2d at 1531-1533). Accordingly, the Eleventh Circuit held the Hillsborough County Ordinances to be invalid, because local regulation in the field had been pre-empted.

[4]The FDA regulations are found at 21 C.F.R. Parts 600, 601, 606, 607, 610 and 640, Subpart G.

The County's brief indicates substantial agreement with AML on the correct principles of pre-emption analysis applicable to the case at bar. However, without advancing persuasive reasons in support of their position, the County argues that the Eleventh Circuit misapplied the principles of pre-emption analysis.

Amici curiae supporting the County argue that the Eleventh Circuit applied incorrect principles of pre-emption analysis in finding that the federal regulatory system pre-empts local legislation. More specifically, the National Association of Counties, *et al.*, with misplaced reliance upon *Fidelity Federal Savings & Loan Ass'n. v. de la Cuesta*, 458 U.S. 141, 102 S.Ct. 3014 (1982) and *Capital Cities Cable, Inc. v. Crisp*, ____ U.S. ____, 104 S.Ct. 2694 (1984), argue that, in the absence of explicit statutory language of pre-emption, a finding of express agency intent to pre-empt is required before agency regulations pre-empt state law. The United States argues that this Court cannot find implied pre-emption where the agency initially indicated a lack of intent to pre-empt local legislation.

The authorities relied upon by the National Association of Counties, *et al.* and by the United States do not, upon proper analysis, stand for the propositions being urged by the *amici curiae* supporting the County. Proper determination of this case does not require a departure from established principles of pre-emption analysis.

For the reasons stated above, and fully discussed in Point II below, the Eleventh Circuit applied the proper legal standard in concluding that the Hillsborough County ordinances at issue are pre-empted by the federal

regulatory system authorized by the Public Health Service Act and effectuated by regulations of the FDA.

For the reasons summarized below and fully discussed in Part III, application of well-settled principles of pre-emption analysis mandates a holding that the conclusion reached by the Eleventh Circuit, that the challenged ordinances are wholly pre-empted and cannot stand, was correct.

As recently as June 1984, this Court restated the three possible bases for a determination that local legislation has been pre-empted by federal law: (1) in enacting a federal statute, Congress may explicitly state that it intends to pre-empt state law (express pre-emption); (2) in the absence of language expressly pre-empting state legislation,[5] Congress may, nevertheless, indicate its intent to occupy an entire field of regulation, thereby precluding the states from regulating in that area (implied pre-emption); and (3) even in the absence of express or implied congressional intent to displace state law in its entirety, state law may be pre-empted to the extent that the state law actually conflicts with federal law, either when compliance with both state and federal law is impossible, or when the state law presents an obstacle to the purposes and objectives of Congress (obstacle). *Capital Cities Cable, Inc. v. Crisp, supra*, ____ U.S. at ____, 104 S.Ct. at 2700-01.

The principles enunciated in *Capital Cities* are consistent with, and follow, an established line of decisions

[5]Local ordinances are treated as are state statutes for these purposes. *City of New Orleans v. Dukes*, 427 U.S. 297, 96 S.Ct. 2513 (1976).

of this Court. *See, e.g., Michigan Canners & Freezers Ass'n. v. Agricultural Marketing and Bargaining Board.* ___ U.S. ___, 104 S.Ct. 2518 (1984); *Jones v. Rath Packing Co.*, 430 U.S. 519, 97 S.Ct. 1305 (1977); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 67 S.Ct. 1146 (1947); *Bethlehem Steel Co. v. New York State Labor Relations Bd.*, 330 U.S. 767, 67 S.Ct. 1026 (1947). Federal regulations can have the same pre-emptive effect as do federal statutes. *Fidelity Federal v. de la Cuesta, supra,* ___ U.S. at ___, 102 S.Ct. at 3022; *Capital Cities Cable, Inc. v. Crisp,* ___ U.S. at ___, 104 S.Ct. at 2700.

The case at bar is not an instance in which Congress or the FDA has explicitly stated an intent to pre-empt. Therefore, the first possible basis for a finding of pre-emption is inapplicable.

In the absence of express pre-emption, an analysis of whether Congress or the appropriate federal agency has impliedly pre-empted local law is required. There are two instances in which implied pre-emption will be found: (i) where the federal system of regulation is so pervasive as to fill the field of regulation, or (ii) where the federal interest in the area regulated is dominant over any local interest.

The first test for implicit federal pre-emption is met in the case at bar because the federal system for regulation of blood and blood products, established pursuant to Section 351 of the Public Health Service Act ("the Act"), is so pervasive as to leave no room for state regulation of the plasmapheresis industry. Section 351 of the Act requires federal licensing of each

establishment producing a biological product, federal licensing of each product to ensure safety, purity and potency, and federal standards for packing and labeling of the product. The FDA regulations implementing the Act contain a section dealing specifically with "Source Plasma (Human)," as well as more general sections which apply to the plasmapheresis procedure itself. The federal regulatory system is so comprehensive and extensive as to compel the conclusion that Congress and the FDA have left no room for state regulation in the field of plasmapheresis.

The second test for implicit pre-emption is met, in that at least in the areas of product purity, donor safety and adequate plasma supply, the federal interest in the plasmapheresis field is so dominant that local legislation is precluded. Section 351 of the Act prohibits the sale or transportation of any blood or blood product which has not been propagated or manufactured and prepared at a federally licensed establishment. Section 361 of the Act (42 U.S.C. §264) authorizes the FDA to promulgate such regulations as are necessary to prevent the introduction, transmission, or spread of blood related communicable disease from one state to another. This necessarily requires the FDA to exercise its authority to regulate a potential disease-causing substance from the source of its collection through its subsequent processing (or manufacture) and shipment. The FDA, in promulgating the regulations concerning biological products, established a comprehensive National Blood Policy and employed the full regulatory authorities vested in the federal government to assure uniform adherence to the highest attainable standards of practice in blood banking, including plasmapheresis. The statutory

language and the regulatory framework indicate that Congress intended uniform national standards to promote product purity, donor safety and an adequate plasma supply.

The County concedes that the concern of its local legislation is the source of the blood product, that is, the donor. The concern for donor safety, then, is shared by the County and the FDA. However, given the federal congressional and regulatory intent to establish a uniform, comprehensive national program in the area, and the FDA's duty to issue all regulations it deems necessary to effect that goal, it is apparent that Congress intended uniform national standards that would foreclose the imposition of different or more stringent local requirements.

Because federal regulation of plasma and plasmapheresis is so pervasive, and because the federal interest in regulating the field is so dominant as to preclude enforcement of local laws on the subject, the federal regulatory system implicitly pre-empts enforcement of the County's ordinances.

Even if Congress and the FDA have not implicitly pre-empted state regulation of the plasmapheresis industry, enforcement of the challenged local legislation would result in both an irreconcilable conflict with federal regulations and a substantial obstacle to the full attainment of congressional objects and purposes in regulating blood and blood products. The County ordinances, including a restrictive donor registration requirement, a pre-registration hepatitis test, a pre-donation breath analysis for alcohol content and detailed recordkeeping and reporting requirements, impose

burdensome and expensive requirements in addition to the extensive federal regulatory system. If enforced, the County's legislation would conflict with federal regulation authorizing the collection of hepatitis plasma for vaccine manufacture and would frustrate the congressional goals of ensuring a safe and adequate blood supply and ensuring a continued supply of healthy donors.

ARGUMENT

POINT I

THE DECISION OF THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT SHOULD BE SUMMARILY AFFIRMED.

AML filed its Motion to Affirm with this Court on June 27, 1984. For the reasons stated therein, this Court should now, AML respectfully submits, summarily affirm the decision of the United States Court of Appeals for the Eleventh Circuit.

The controlling issues have now been fully briefed in this Court, and, under the current and well-settled state of the law of pre-emption, it is abundantly clear, for the reasons fully discussed in Point II below, that the Eleventh Circuit applied the appropriate legal principles in determining that Hillsborough County Ordinances 80-11 and 80-12 are pre-empted by federal law. For the reasons fully discussed in Points III and IV below, the Eleventh Circuit correctly determined, under the tests set forth in *Pennsylvania v. Nelson*, 350 U.S. 497, 76 S.Ct. 477 (1956), that the Hillsborough

County ordinances were pre-empted by the federal regulatory system.

POINT II

THE COURT OF APPEALS APPLIED THE PROPER LEGAL STANDARD IN DETERMINING THAT THE CHALLENGED LOCAL LEGISLATION WAS PRE-EMPTED.

A. The basic principles of pre-emption analysis are well settled and free of doubt.

It is axiomatic that the doctrine of federal pre-emption is grounded upon the Supremacy Clause of the United States Constitution, Article VI, clause 2:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; . . . shall be the supreme Law of the Land; . . .

Since as early as 1824, the Supremacy Clause, as the foundation for the doctrine of federal pre-emption, has been interpreted and applied to invalidate local laws that "interfere with, or are contrary to" federal law. *Gibbons v. Ogden*, 9 Wheat. 1, 211 (1824).

It is also firmly established that "(f)ederal regulations have no less pre-emptive effect than federal statutes." *Fidelity Federal v. de la Cuesta, supra*, 458 U.S. at 153-54, 102 S.Ct. at 3022; *Capital Cities Cable, Inc. v. Crisp*, ____ U.S. at ____, 104 S.Ct. at 2700:

> . . . Under the Supremacy Clause, U.S. Const., Art. VI, cl. 2, the enforcement of a state regulation may be pre-empted by federal law in several circumstances: first, when Congress, in enacting a federal statute, has expressed a clear intent to pre-empt state law, *Jones v. Rath Packing Co.*, 430 U.S. 519, 525, 97 S.Ct. 1305, 1309, 51 L.Ed.2d 604 (1977); second, when it is clear, despite the absence of explicit pre-emptive language, that Congress has intended by legislating comprehensively, to occupy an entire field of regulation and has thereby "left no room for the States to supplement" federal law, *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 1152, 91 L.Ed. 1447 (1947); and, finally, when compliance with both state and federal law is impossible, *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-143, 83 S.Ct. 1210, 1217-1218, 10 L.Ed.2d 248 (1963), or when the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67, 61 S.Ct. 399, 404, 85 L.Ed 581 (1941). See also *Michigan Canners & Freezers Assn. v. Agricultural Marketing and Bargaining Board*, ____ U.S. ____, ____, 104 S.Ct. 2518, ____, 80 L.Ed.2d ____(1984).

And, as we made clear in *Fidelity Federal Savings and Loan Assn. v. De La Cuesta*, 458 U.S. 141, 102 S.Ct. 3014, 78 L.Ed.2d 664 (1982).

> "Federal regulations have no less pre-emptive effect than federal statutes
> . . .

* * *

The cases cited above flow consistently in a long stream of cases expressing these now familiar principles. See, e g.: *Bethlehem Steel Co. v. Allegheny Ludlum Steel Corp.*, 330 U.S. 767, 67 S.Ct. 1026, (1947); *Rice v. Santa Fe Corporation.*, 331 U.S. 218, 67 S.Ct. 1146 (1947); *Jones v. Rath Packing Co.*, 430 U.S. 519, 97 S.Ct. 1305 (1977); *Michigan Canners, supra*, ___ U.S. ___, 104 S.Ct. 2518 (1984).

B. Contrary to the position advanced by the National Association of Counties, a finding of express agency intent to pre-empt is not a prerequisite to a holding that the federal regulatory system governing the plasmapheresis industry pre-empts the challenged Hillsborough County ordinances.

Although the principles set forth above would appear to be certain, the primary substantive disagreements among the parties (and *amici curiae*) in this case arise at this point in the pre-emption analysis.

In the case at bar, the Eleventh Circuit found that the language of the statutes upon which the comprehensive FDA regulatory system is based, the Public Health Service Act and the Federal Food, Drug and Cosmetic Act, does not support a finding of express congressional intent to pre-empt (JA 54-55; 722 F.2d at 1530). From that finding, coupled with an unsound analysis of *Fidelity Federal v. de la Cuesta*, the National Association of Counties asks this Court to adopt an entirely novel approach to pre-emption analysis and to depart from the well settled rules of law expressed above. The National Association of Counties advances the position

that, in the absence of express congressional intent to pre-empt, a finding of pre-emption by agency regulation is proper only if the agency has expressly stated its intent to pre-empt local legislation.[7]

It hardly merits stating that, in accordance with modern day concepts of federalism, Congress frequently provides the statutory basis for federal control over a given field, and delegates to an agency the task of promulgating and enforcing the detailed regulatory system. *Bethlehem Steel Co. v. New York State Labor Relations Bd.*, 330 U.S. 767, 67 S.Ct. 1026 (1947). This, of course, is the context of the case at bar, namely, a congressional enactment stating essential federal principles and policy, with appropriate authority granted to the proper agency to enact controlling regulations. This gives rise to the issue of whether the system of federal regulation has pre-empted local legislation in the field.

In such circumstances, this Court has repeatedly found local regulation to be pre-empted, even without a finding of express agency intent to pre-empt. *Capital Cities Cable, Inc. v. Crisp* ___ U.S. ___, 104 S.Ct. 2694 (1984) (Federal Communications Commission regulations promulgated under Communications Act of 1934); *Jones v. Rath Packing Co.*, 430 U.S. 519, 97 S.Ct. 1305 (1977) (Secretary of Agriculture regulations promulgated under Federal Meat Inspection Act); *Ray v. Atlantic Richfield Co.*, 435 U.S. 151, 98 S.Ct. 988 (1978) (Department of Transportation regulations promulgated under Ports and Waterways Safety Act of 1972); *Franklin National*

[7]Brief of the National Association of Counties, *et. al.*, as *Amici Curiae*, p. 16.

Bank v. New York, 347 U.S. 373, 74 S.Ct. 550 (1954) (Federal Reserve Board Regulations promulgated under Federal Reserve Act).

In short, the National Association of Counties' position represents a radical departure from the established precedent of this Court.

In addition, *Fidelity Federal v. de la Cuesta* simply does not stand for the proposition advanced—that a finding of pre-emption "requires a clear expression of administrative intent to preempt all state efforts, including non-conflicting laws, to regulate the same subject."[8] In fact, *Fidelity Federal v. de la Cuesta* restates the classic principles of pre-emption analysis and explicitly recognizes that "federal regulations have no less pre-emptive effect than federal statutes." ____ U.S. at ____, 102 S.Ct. at 3022. The issue in *Fidelity Federal v. de la Cuesta* was whether the agency expressing the intent to pre-empt did so with proper congressional authority. *Fidelity Federal v. de la Cuesta* cannot be construed to stand for the proposition asserted by the National Association of Counties.

C. The position advanced by the United States is contrary to controlling precedent.

The position advanced by the United States appears to differ from the position of AML in only one, but one quite substantial, respect. The United States acknowledges, as indeed it must, that the subject FDA regulations are "comprehensive" and that:

---

[8]Brief of National Association of Counties, *et. al.*, as *Amici Curiae*, p. 16.

> [t]he purpose of the FDA regulations is to establish nationwide standards necessary to provide an adequate supply of safe, pure and potent blood, blood components, and blood products, *as well, as to protect the health of blood donors.*[9]

The United States argues, however, that because a comment made at the time the initial regulations were proposed indicates a lack of intent to pre-empt, this Court cannot find implied pre-emption despite the facts that the regulations are comprehensive in scope, and concern an area in which the federal interest is dominant, and the County ordinances have the same goal as the federal regulations. However, later comments by the Commissioner indicate that the agency soon thereafter felt constrained to take steps to ensure that the plasmaphleresis regulations were uniform, comprehensive and applicable nationwide. *See e.g.*, 39 *Fed. Reg.* 18614-15 (1974). The present scope of the federal regulations should be considered by the Court in determining if a finding of pre-emption is now appropriate. *Edgar v. MITE Corp.*, 457 U.S. 624, 633, 102 S.Ct. 2629, 2636 (1982).

AML's position, that a federal regulatory system impliedly pre-empts the entire field of regulation when (i) the federal law fills the field by its pervasiveness or (ii) the federal law regulates a field of dominant federal interest, is fully supported by the cases cited in Point II, B above. The fact that the United States concedes the pervasiveness of the FDA plasmapheresis regulations,

---

[9]Brief for the United States, as *Amicus Curiae*, p. 7 (emphasis supplied).

and the importance of the national interest thusly served, adds substantial weight to AML's position that the Eleventh Circuit's holding of implicit federal pre-emption of the field of plasmapheresis was sound and should be affirmed.

Of particular importance is the fact that the United States admits that the federal regulations have as one of their purposes the same purpose as the County ordinances, namely the protection of the health of the donors. The law is well settled that when local legislation has the same purpose as a comprehensive federal regulatory system, local legislation in any area of that field is pre-empted. *Ray v. Atlantic Richfield Company*, 435 U.S. 151, 98 S.Ct. 988 (1978).

The facts in *Ray* are strikingly similar to those in the case at bar. Pursuant to statutory authority, the Secretary of Transportation was to promulgate "comprehensive minimum standards" for the design and structure of certain cargo carrying vessels. After promulgating such standards, the Secretary was to then provide for inspection for compliance with the minimum requirements, and to issue certificates if the federal standards were satisfied. The State of Washington attempted to impose additional and more stringent requirements to accomplish the same goal as the Secretary's, namely vessel safety. Applying well established principles of pre-emption analysis, this Court held that "[t]he Supremacy Clause dictates that the federal judgment that a vessel is safe to navigate United States waters prevails over the contrary state judgment." *Ray v. Atlantic Richfield Co.*, 435 U.S. at 165, 98 S.Ct. at 998. This Court went on to find that to allow the state to impose additional and more stringent

requirements on vessel design and safety would frustrate the congressional purpose of establishing uniform national standards, which if met, allow a vessel to operate. Thus, because Hillsborough County has admittedly "enacted a regulatory scheme governing [the area covered by the FDA regulations]",[10] and that scheme imposes additional and more stringent requirements than those imposed by federal law, the local legislation is pre-empted entirely.

D. The Court of Appeals applied the proper legal standard in determining that the Hillsborough County ordinances are pre-empted.

Thus, for the reasons stated above, the correct legal standard was utilized by the Eleventh Circuit in its analysis of this case. And, as will be demonstrated in Point III below, application of those well established pre-emption standards compels the conclusion that the challenged County ordinances are pre-empted.

POINT III

PROPER APPLICATION OF WELL-SETTLED PRINCIPLES OF IMPLIED PRE-EMPTION ANALYSIS MANDATES THE CONCLUSION THAT THE CHALLENGED ORDINANCES ARE WHOLLY PRE-EMPTED AND CANNOT STAND.

The Eleventh Circuit, in determining that the federal system for regulating blood plasma and plasmapheresis

[10]Brief for the United States, as *Amicus Curiae*, p. 7.

implicitly pre-empted the County's regulation of the area, applied the tests set forth in *Pennsylvania v. Nelson*, 350 U.S. 497, 76 S.Ct. 477 (1956), the identical tests recently restated by this Court in *Fidelity Federal v. de la Cuesta, supra*, 458 U.S. 141, ____, 102 S.Ct. 3014, 3022 (1982): (i) whether the federal scheme is so pervasive as to make reasonable the inference that Congress left no room for the states to supplement it, or (ii) whether the federal system of regulation controls a field in which the federal interest is so dominant that the federal system must be assumed to preclude enforcement of state laws on the same subject.

The Eleventh Circuit was eminently correct in holding that, based upon the criteria set forth in *Pennsylvania v. Nelson*, as restated in *Fidelity Federal v. de la Cuesta*, the County regulation of plasma and plasmapheresis is implicitly pre-empted by the federal system regulating the area.

A. Federal regulation of blood plasma and plasmapheresis is so pervasive as to leave no room for local regulation of the area.

The first test for determining the existence of implied federal pre-emption is whether federal regulation of the area is so pervasive as to make reasonable the inference that Congress left no room for the states to supplement it. *Pennsylvania v. Nelson*, 350 U.S. at 502, 76 S.Ct. at 480. In the case at bar, the federal system for regulation of plasmapheresis is so extensive as to require such an inference.

As the Eleventh Circuit noted, Section 351 of the Public Health Service Act (the "Act") requires federal licensing of each establishment producing a biological product, federal licensing of each such product to ensure safety, purity and potency, and federal standards for packaging and labeling of the product. 42 U.S.C. §262 (1982). Section 351 and Section 361 (42 U.S.C. §264) of the Act delegate to the FDA the authority to promulgate the rules and regulations required to implement the Act. (JA 56; 722 F.2d at 1531).

The regulations implementing the Act include a section dealing specifically with "Source Plasma (Human)," which is defined as the fluid portion of human blood collected by plasmapheresis and intended as source material for further manufacturing use. 21 C.F.R. §640.60-640.76 (1983).[11] Other portions of the regulations promulgated pursuant to the Act also apply to, and regulate, virtually every aspect of the plasmapheresis industry.[12] *Id.*

---

[11]The regulations prescribe rules as to consent of a prospective donor, medical supervision of the procedure, suitability of donors, method of collection, requirements of the plasmapheresis procedure, immunization of donors, testing for hepatitis, processing of the blood, pooling, inspection, labeling, manufacturing responsibility, records, reporting of fatal donor reactions, modification of source plasma, alternate procedures, and products stored or shipped at unacceptable temperatures (JA 56, fn.4; 722 F.2d at 1531, fn.4).

[12]The subjects included within the remaining regulations are establishment standards and inspections, 21 C.F.R. §§600.3-22 (1983); licensing, 21 C.F.R. §§601.1-601.33 (1983); good manufacturing practices for blood and blood components, 21 C.F.R. §§606.3-606.170 (1983) (with specific sections relating to personnel, facilities, equipment, supplies and reagents, standard operating procedures, finished product and laboratory controls, labeling, records, and reports);

Clearly, as found by the Eleventh Circuit, the federal regulations are broad in their scope and cover virtually every phase of the plasmapheresis process. The federal regulatory system is so comprehensive and extensive that the only reasonable inference that may be drawn is that Congress and the FDA have left no room for local regulation in the plasmapheresis field.

B. At least in the areas of product purity, donor safety and adequate plasma supply, the federal interest is so dominant that local legislation is precluded.

The second basis for a finding of implicit federal pre-emption is a finding that the federal regulatory system covers a field in which the federal interest is so dominant that the federal system must be assumed to preclude enforcement of state laws on the same subject. *Pennsylvania v. Nelson*, 350 U.S. at 504, 76 S.Ct. at 481. In the case at bar, the federal interest in ensuring a safe and adequate supply of blood and blood components, and in ensuring the safety of the donors, as demonstrated by congressional act and federal agency regulation, dominates over any local interest in those areas.

Again, as found by the Eleventh Circuit, Congress and the FDA have maintained extensive and comprehensive control over the nation's blood collection system since 1946. 38 *Fed. Reg.* 2966 (1973). The collection

---

(Footnote 12 Continued)

establishment registration and product listing, 21 C.F.R. §§607.3-607.65 (1983); general biological products standards, 21 C.F.R. §610.65 (1983) (including standards of potency, hepatitis requirements, dating periods, and labeling standards) (JA 56, fn.5; 722 F.2d at 1531, fn.5).

of blood is an area of national concern, for "[h]uman blood is a priceless resource." 39 *Fed. Reg.* 18614 (1974) (JA 57; 722 F.2d at 1531).

Section 351 of the Act prohibits the sale or transportation of any blood or blood product that has not been propagated (or manufactured) and prepared at a federally licensed establishment. Pursuant to Section 361 of the Act (42 U.S.C. §264) and under the authority delegated under 21 C.F.R. §20.21, the FDA is authorized to promulgate such regulations as are necessary to prevent the introduction, transmission, or spread of blood related communicable disease from one state to another, necessarily requiring the FDA to exercise its authority to regulate a potential disease-causing substance from the source of its collection through its subsequent processing (or manufacture) and shipment. 39 *Fed. Reg.* 18614 (1974).[13]

In promulgating regulations concerning good manufacturing practices for blood and blood components, the Commissioner of Food and Drugs stated that:

> The promulgation of standards for these biological drugs is part of an existing effort to increase the quality of blood related health care in this country. Pursuant to the findings of a special Task Force in Blood Banking, the Secretary of Health, Education, and Welfare has established a *comprehensive National Blood*

---

[13]In 1974, the FDA expressly acknowledged that the inspection or licensing provisions enacted by approximately ten states were inadequate to protect against the spread of hepatitis in blood products. 39 *Fed. Reg.* 18614-18615 (1974).

> *Policy*. One of the fundamental methods prescribed by the Secretary to implement the policy is to "employ the full regulatory authorities now vested in the Federal Government * * * for the purpose of assuring uniform adherence to the highest attainable standards of practice in blood banking, including plasmapheresis and plasma fractionation."

39 *Fed. Reg.* 18614 (1974) (emphasis supplied).

The FDA, therefore, has developed a "comprehensive regulatory program" concerning blood and blood products.[14] The FDA's express purposes in promulgating regulations to implement that program are to ensure a safe and adequate supply of blood and blood products and to ensure a continuous and healthy donor population. 41 *Fed. Reg.* 10762-10763 (1976); 39 *Fed. Reg.* 26161-26162 (1974); 39 *Fed. Reg.* 18615 (1974).

The United States, in its Brief, acknowledges that, insofar as those goals are concerned, the federal interest so dominates as to foreclose local legislation on the subject.

> The federal government has required vendors nationwide to be subject to the same minimum product and donor safety standards to further the two-fold interest in ensuring that the national supply of safe, pure, and potent blood plasma remains adequate to meet the nation's health care needs and in protecting the health of donors for their own sake and to provide a healthy donor population. To that extent, the federal interest in plasmapheresis is dominant and the states are foreclosed from promoting a contrary policy.[15]

[14]*See, supra*, fn. 12 and 13.

The County attempts to create a distinction between the purposes of the federal regulation and those of the local ordinances, asserting that the purpose of the local legislation is to protect the health of the donor of the plasma, while the purpose of the federal regulations is to ensure the purity and adequacy of supply of the product (Appellant's Brief on the Merits, p. 10). However, as demonstrated above, the distinction sought to be made by the County is illusory.

The federal regulatory system aims at ensuring an adequate supply of blood and blood products, maintaining product safety and protecting and maintaining a sufficient supply of healthy donors. Congress, insofar as those aims are concerned, has entrusted to the FDA the duty of promulgating all regulations necessary to meet those ends. Section 351 of the Act, and the attendant regulatory framework, clearly demonstrates that Congress intended uniform national standards in the areas of product safety and supply and donor protection that would foreclose the imposition of more stringent local requirements in those areas. *Ray v. Atlantic Richfield Co.*, 435 U.S. at 164, 98 S.Ct. at 998 (1978).

AML does not, of course, assert that, by reason of the federal regulatory system, it is free to ignore local

[15]Brief of the United States, as *Amicus Curiae*, p. 23.

regulation in areas not covered by the federal regulations, such as local occupational licensing or general health and safety requirements. See, e.g., *Huron Portland Cement Co. v. City of Detroit, Michigan*, 362 U.S. 440, 80 S.Ct. 813 (1960) (federal approval and licensing of vessels to ensure seagoing safety did not preclude enforcement of municipal smoke abatement ordinance); *Pacific Gas & Electric Co. v. State Energy Resources Conservation & Development Comm'n.*, 461 U.S. 190, 103 S.Ct. 1713 (1983) (federal regulation of radiological safety in construction and operation of nuclear power plants did not preclude state regulation concerning need, reliability and cost). However, the local ordinances at issue in this case relate only to the precise areas encompassed by the federal regulations.

The County attempts to regulate in areas which have been identified as being of dominant federal concern. The County is precluded from imposing requirements which are different from, or more stringent than those dictated to promote the comprehensive national program in that area, and, thus the County ordinances, are impliedly pre-empted by the federal regulatory system.

POINT IV

BECAUSE ENFORCEMENT OF THE CHALLENGED LOCAL LEGISLATION WOULD RESULT IN BOTH AN IRRECONCILABLE CONFLICT WITH FEDERAL REGULATIONS AND A SUBSTANTIAL OBSTACLE TO FULL ATTAINMENT OF CONGRESSIONALLY MANDATED OBJECTS AND PURPOSES, THE LOCAL LEGISLATION IS PRE-EMPTED.

Even if the pervasiveness of the federal regulations (Point III, A) and the dominance of the federal interest in the subject matter of those regulations (Point III, B) were not enough to imply pre-emption of the County ordinances, enforcement of the ordinances would conflict with the federal regulations and stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress in establishing a national policy with regard to blood and blood products. These circumstances alone compel a finding that the challenged legislation is pre-empted. *Capital Cities Cable, Inc. v. Crisp*, ____ U.S. at ____, 104 S.Ct. at 2700; *Michigan Canners, supra*, ____ U.S. at ____, 104 S.Ct. at 2523; *Fidelity Federal v. de la Cuesta, supra*, ____ U.S. at ____, 102 S.Ct. at 3022.

The United States recognizes a conflict between the County ordinances and the federal regulations. If the County ordinances were to be enforced, plasmapheresis centers in Hillsborough County would be prevented from collecting plasma necessary for

production of hepatitis vaccine.[16] This conflict alone mandates a holding of pre-emption.

More substantially, enforcement of the County ordinances would stand as a serious obstacle to the expressly stated federal goal to "insure there is a continued healthy donor population to serve as a source of plasma." 37 *Fed. Reg.* 17420 (1972). In fact, AML's evidence at trial demonstrated that enforcement of the County ordinances would render the continued existence of AML's plasma center in Tampa economically impossible by substantially increasing costs of plasma production, while, at the same time, substantially reducing the donor population.

In particular, enforcement of the County ordinances would have such a negative effect upon local plasma centers that the donor population would be significantly reduced, resulting, obviously, in a diminished supply of available plasma. The evidence at trial indicated that enforcement of the County ordinances would result in an increase in direct costs of plasma production by $1.50 per litre, and a total increase in production costs (including both direct and indirect costs) of $7.00 per litre of plasma, an increase of approximately 15% in the total cost of production (TR 49-52; AML Trial Exhibit 19). In fact, prior experiences with a virtually identical set of ordinances indicate that the number of plasma centers would be reduced, in addition to reducing the donor population. Similar ordinances have been in effect in Miami, and since their enactment the number of plasma centers has been reduced from eleven until only two currently remain (AML Trial Exhibits 4 and 5).

[16]Brief of United States, as *Amicus Curiae*, pp. 29-30.

Donor population would be reduced by the complete elimination of what is known as the "casual donor." A casual donor is a donor who does not regularly engage in a systematic plasmapheresis program, but who does so only occasionally, usually at times separated over many months. Casual donors would be effectively excluded from engaging in plasmapheresis under the County ordinances because they would need County donor identification cards, which would be burdensome to obtain and would be valid for only six months. Additionally, those donors who participate elsewhere in a plasmapheresis program on a regular basis, but who find themselves in Hillsborough County only for a short period of time, would be effectively excluded from continuing to participate as plasma donors while in the County of Hillsborough (TR 54-55).

While it is true that the County has a legitimate interest in protecting the health and safety of its citizens, any such protection provided by the subject ordinances is illusory. None of the features of the County regulations accomplishes a purpose that the federal regulatory system does not accomplish, and none provides protection to the people of Hillsborough County not afforded by the comprehensive federal regulations.

Because enforcement of the County ordinances would, in the above respects, stand as an obstacle to the accomplishment and execution of the purposes of Congress in establishing a national blood policy, the ordinances are pre-empted by the federal regulatory system.

CONCLUSION

The Eleventh Circuit properly determined, based upon criteria set forth by this Court, that the subject Ordinances are pre-empted by federal regulation. For the reasons stated herein, the judgment below should be affirmed.

Respectfully submitted,

LARRY A. STUMPF
Counsel of Record
VICTORIA L. BADEN
Members, United States
Supreme Court Bar

FINLEY, KUMBLE, WAGNER, HEINE,
UNDERBERG, MANLEY & CASEY
Counsel for Appellee
Suite 1000, Flagship Center
777 Brickell Avenue
Miami, Florida 33131
(305) 371-2600

CHARLES F. JOHNS,
On the Brief

CERTIFICATE OF SERVICE

All parties required to be served have been served by depositing on this 29th day of March, 1985 three printed copies of this document in a U.S. Post Office, with first class postage prepaid, addressed to counsel of record at his or her post office address as follows:

Joe Horn Mount, Esq.
Hillsborough County Attorney
Counsel for Appellants
P.O. Box 1110
Tampa, Florida 33601

Paul J. Larkin, Jr., Esq.
Counsel for Amicus,
United States Government
Department of Justice
Solicitor General's Office
10th and Constitution Ave.
Room 5634
Washington, D.C. 20004

Joyce Holmes Benjamin, Esq.
Counsel for Amicus,
The Academy for State and
Local Government
The State and Local Legal Center
Suite 349
444 North Capital Street, N.W.
Washington, D.C. 20001

Richard Landfield, Esq.
Landfield, Becker & Green
Counsel for Amicus,
American Blood Resources
Association
1220 Nineteenth Street, N.W.
Washington, D.C. 20036

/s/ Larry A. Stumpf

LARRY A. STUMPF
Counsel of Record
Member, United States Supreme
Court Bar

FINLEY, KUMBLE, WAGNER, HEINE,
UNDERBERG, MANLEY & CASEY
Counsel for Appellee
Suite 1000, Flagship Center
777 Brickell Avenue
Miami, Florida 33131
(305) 371-2600

No. 83-1925

IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

HILLSBOROUGH COUNTY, FLORIDA, *Et Al.*,
Appellants,

v.

AUTOMATED MEDICAL LABORATORIES, INC.,
Appellee.

On Appeal From the United States Court of Appeals for the Eleventh Circuit

---

BRIEF OF AMERICAN BLOOD RESOURCES ASSOCIATION AND FLORIDA ASSOCIATION OF PLASMAPHERESIS ESTABLISHMENTS AS *AMICI CURIAE* IN SUPPORT OF APPELLEE

RICHARD LANDFIELD
Counsel of Record
WILLIAM W. BECKER
LANDFIELD, BECKER & GREEN
1220 Nineteenth Street, N.W.
Suite 201
Washington, D.C. 20036
(202) 775-0300
Counsel for the Amici Curiae

PRESS OF BYRON S. ADAMS, WASHINGTON, D.C. (202) 347-8203

QUESTION PRESENTED

Does a comprehensive scheme of Federal regulation of plasmapheresis, designed to promote a national policy for uniformity in blood banking and plasmapheresis, and to assure both donor safety and product quality, preempt Hillsborough County, Florida regulations that conflict with the Federal regulations yet do not achieve any legitimate purpose not already covered in the Federal Regulations?

TABLE OF CONTENTS

TABLE OF AUTHORITIES

TABLE OF AUTHORITIES continued

TABLE OF AUTHORITIES continued

TABLE OF AUTHORITIES continued

TABLE OF AUTHORITIES continued

TABLE OF AUTHORITIES continued

IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

No. 83-1925

HILLSBOROUGH COUNTY, FLORIDA, *Et Al.*,
Appellants,

v.

AUTOMATED MEDICAL LABORATORIES, INC.,
Appellee.

On Appeal From the United States Court of Appeals for the Eleventh Circuit

BRIEF OF AMERICAN BLOOD RESOURCES ASSOCIATION (ABRA) AND FLORIDA ASSOCIATION OF PLASMAPHERESIS ESTABLISHMENTS (FAPE) AS *AMICI CURIAE* IN SUPPORT OF APPELLEE

INTEREST OF *AMICI CURIAE*

ABRA is a not-for-profit trade association. Its approximately eighty members* operate about three hundred plasma collection facilities, manufacture plasma-based pharmaceuticals, chemistry controls and blood banking reagents, and engage in research and development of new products. ABRA's members, whose facilities are located in about 212 communities in 42 states, produce and distribute about 70% of the plasma products used in the United States.[1]

* A list, pursuant to rule 28.1, of corporations which are (1) members of American Blood Resources Association (ABRA), or Florida Association of Plasmapheresis Establishments (FAPE), *Amici Curiae* herein, (2) parents or affiliates of members of ABRA or FAPE, or (3) not included in categories (1) or (2) but which may have an interest in this case has been lodged with the Clerk of this Court. The list is believed to include all corporations now known by ABRA to be engaged, directly or indirectly, in plasmapheresis or the manufacture and distribution of plasma products.

[1] There are approximately 350 plasma collection centers in the United

ABRA's members include sole proprietorships as well as large multinational corporations.[2] FAPE, with 11 members operating 20 plasma centers in Florida, is affiliated with ABRA.[3] It represents Florida plasmapheresis centers regarding state legislative issues as well as local concerns, such as arise out of the Ordinances challenged in this case.

Plasma, the clear fluid portion of the blood, contains a variety of protein substances essential for manufacture into products used extensively in the health care industry.[4] "Injectables," or products made from plasma for human use, include volume expanders, antihemophilic factor (AHF), and such immune products as Rh immune globulin and hepatitis vaccine.[5] ABRA's members furnish about 80% of

States. Industry estimates that it recruits and collects plasma from some 46,000 donors, by plasmapheresis, each day, representing an annual total of 10 million plasmapheresis collections. Those collections will meet about 60 percent of the world's raw plasma requirements. In 1983, the commercial plasma industry produced an estimated 6 million liters of source plasma, 4.7 million liters for fractionation into pharmaceuticals and manufacture of diagnostic products, and 1.3 million liters for export.

[2] ABRA seeks to develop a sound regulatory framework designed to promote donor safety and product safety and efficacy, encouragement of better understanding of the proprietary plasma industry, and adherence by its members to a code of ethical practice. ABRA's Code of Ethics is included as Appendix A hereto. ABRA's objectives are achieved through a variety of activities, including publication of *Plasma Quarterly*, a scientific and management journal; sponsorship of an annual "Plasma Forum" which attracts the world's leading authorities on scientific and technological aspects of plasmapheresis; and liaison with FDA officials and Congress regarding plasma regulatory issues.

[3] Appellee Automated Medical Laboratories, Inc., is a member of ABRA and FAPE.

[4] Source Plasma (Human) is a product defined as plasma obtained by plasmapheresis. 21 C.F.R. § 640.60. In the plasmapheresis procedure, blood is removed from a human donor, the plasma and red blood cells are separated, and the red cells are returned to the donor.

[5] Hepatitis vaccine, a relatively new product, is manufactured using plasma which contains hepatitis antigen. Hepatitis vaccine may reduce the incidence of Hepatitis B, a major health problem. Rh immune globulin is

the AHF used by this country's approximately 20,000 hemophiliacs. Since AHF became available in the late 1960s, it has greatly improved the quality of life and life expectancy of hemophiliacs since it allows home care treatment and substantially reduces the amount of hospitalization and health care services needed by hemophiliacs. *See*, generally, Aledort, "The Availability of Plasma Products and the Care of Hemophilia Patients," 246 *J.A.M.A.* 157 (July 10, 1981); Massie and Massie, *Journey* (Knopf, 1976) (the account of raising a hemophiliac son); Child, "Hemophiliacs and Plasma," *Plasma Forum* 25 (McNally & Loftin, West 1979). Plasma is also manufactured into important "non-injectable" products such as blood grouping and typing sera and other laboratory and diagnostic reagents.[6]

ABRA, FAPE and their members have a strong interest in the outcome of this case because it may adversely affect necessary uniformity in the application of regulations and the adequacy of the supply of plasma and plasma products. Although the Federal government determined what regulatory measures were necessary to promote both donor safety and product quality and at the same time assure that there

manufactured using plasma containing Rh-antibody. Each year approximately 320,000 women will deliver Rh positive infants. In the past, those deliveries would have resulted in a 10 percent incidence of potential brain damage or death to the newborn. Since the introduction of Rh immune globulin in the late '60s, more than 2,000 deaths and thousands more injuries have been prevented. Probably the most widely used plasma products are protein replacement fluids used extensively as volume expanders for burn patients, in surgery, and in treatment of trauma.

[6] Blood grouping and typing sera are used in blood banking to assure proper blood grouping and typing. In the past year, there were over 14 million blood components prepared and over 3 million patient transfusions. Those activities could not have occurred safely without high quality plasma products. Every hospital patient benefits from plasma based reagents and diagnostics. For example, a standard admissions routine, the complete blood count, requires plasma based control reagents. Some reagents can be made from plasma from only one or a handful of individuals in the country who possess the rare antibodies needed. Reagents and typing sera rely on commercial plasma collection almost exclusively.

is an adequate source of plasma for products used in the health care industry, Hillsborough County has determined that FDA's donor safety measures were inadequate and adopted the Ordinances. These *Amici* believe that the County's regulations will produce shortages of products like AHF and Rh immune globulin, significantly impacting the hemophiliac community and the health of newborn babies. The entire health care community will be affected. The County, like any other local jurisdiction, is not concerned about the implications of its regulatory actions on the availability or price of plasma and plasma products and thus produced an independent regulatory scheme in conflict with the Federal regulations.

STATEMENT OF THE CASE

A. *Plasmapheresis, Donors and Centers.* Because plasmapheresis takes much longer than whole blood donations, the commercial industry evolved and pays donors for their time. Plasmapheresis may safely be done twice a week because the red blood cells are returned to the donor. 21 C.F.R. § 640.65.[7] Intensive plasmapheresis, regulated under Federal law, is recognized to be safe for the donor.[8]

[7] Generally, a person involved in a regular plasmapheresis program donates plasma between 40 and 60 times per year.

[8] See *e.g.*, Office of Technology Assessment, U.S. Congress "Blood Policy and Technology," Report H-260 (OTA), at 40-41 (1985); FDA Panel on Review of Blood and Blood Derivatives, "Human Plasma as a Source for Fractionation Products," (Draft Report, Nov. 15, 1979); Dawson, *et al.*, "Protein and Hematocrit Value in Long-Term Plasmapheresis Donors," 1 *Plasma Quarterly* 13 (February 1979); Salvaggio, "The Effect of Prolonged Plasmapheresis in Immunoglobulins, Other Serum Proteins, Delayed Hypersensitivity and Phytohemagglutinin, Induced Lymphocyte Transformation," 1 *Plasma Quarterly* 44 (June 1979); Ascari, "Effects on Protein Components during Plasmapheresis for Six Months to Six Years," *Plasma Forum* 119 (ARBA 1980); Cohen, et al., "Hemotologic and Biochemical Observations During Health Surveillance of Plasmapheresis Donors," *Plasma Forum III* 201 (ABRA 1981); Dawson *et al.*, "Laboratory Findings on Long Term Plasmapheresis Donors: Protein Levels," *Plasma Forum III* 209 (ARBA 1981).

Although the stereotype plasma donor is a skid-row alcoholic or narcotics addict, this is far from accurate: blue collar workers, housewives, and university students are the principal donors.[9]

B. *FDA's Plasmapheresis Regulations.* FDA regulates plasmapheresis and blood banking pursuant to comprehensive regulations promulgated under Section 351 of the Public Health Service Act ("PHS Act"), 42 U.S.C. § 262 (1982), and the drug provisions of the Federal Food, Drug and Cosmetic Act ("FDC Act"), 21 U.S.C. §§ 301 *et seq.*[10] These regulations carefully balance the need for donor safety and product quality against the need to assure an adequate supply of plasma. In addition to provisions on donor eligibility, the regulations contain provisions relating to, among other things, establishment and product

[9] Rodell, "Profile of 6000 New Plasmapheresis Donors," 5 *Plasma Quarterly* 42, 57 (Spring 1983). This study of data on over 14,000 donors at more than 20 locations in a dozen states revealed that 77% are white, nearly 70% are under the age of 30, 86% are under 40. Eighty percent of the donors are male. Almost 32% are college students. Most of the balance are blue collar workers or house wives. In another study, industry members characterized the locations of their centers. Most plasma centers—about 60%—are in professional, college or university areas. Residential and industrial areas account for a small percentage, 15%. Fahle, "The Source Plasma Industry: Statistical Report, 1979," 3 *Plasma Quarterly* 68, 69 (Sept. 1981).

[10] Approximately 110 pages of regulations apply to blood and blood products. These reflect in elaborate detail, the requirements of PHS Act Section 351. The present Source Plasma (Human) regulations originated in a 1972 proposal. FDA worked with a panel of experts to craft requirements designed to achieve twin goals of (1) product safety and efficacy and (2) donor safety. Donor safety was emphasized from the very beginning:

> To insure there is a ***continued healthy donor population to serve as a source of plasma*** to be used in the manufacture, by the fractionation technique, of safe, pure, and potent and blood products, the Commissioner is including in these proposed additional standards for Source Plasma (Human) ***specific provisions designed to protect the health and well-being of the donor.***

37 *Fed. Reg.* 17,420 (1972) (emphasis added).

licenses, annual or periodic inspections, good manufacturing practices, storage, labelling, records, reports, and standards for derivatives and reagents. 21 C.F.R., Parts 600, 601, 606, 607, 610, 640, 660 and 680. These regulations operate as an integrated whole and cannot be segmented. FDA also frequently issues guidelines and reviews plasma center operating procedures as part of its regulatory program. Plasma industry activities are regulated, in effect, from "soup to nuts."

Of most relevance here are the regulations expressly relating to donor health and safety. Donor suitability is carefully delineated. 21 C.F.R. § 640.63. A potential plasma donor must undergo a well-defined medical examination performed by a physician employed by the plasmapheresis facility and show satisfactory results for such tests as urinalysis, syphilis, total plasma protein, and specific protein composition. At the initial and each subsequent donation, donor center staff must ask questions regarding donor health, follow specific procedures relating to Acquired Immune Deficiency Syndrome (AIDS), and perform tests, including temperature, blood pressure, pulse, total protein and hematocrit. As a result of these tests, a donor's suitability—including the possibility of overbleeding—is evaluated. A donor's initial exam and processing generally takes three to four hours. Each unit is subsequently tested for hepatitis antigen. 21 C.F.R. § 640.67. Routine testing for the antibody to the causative agents of AIDS is now being implemented. Every four months the protein composition test and syphilis test are repeated, and the physician must review laboratory data and the donor records. 21 C.F.R. § 640.65. Annually, the urinalysis and physician's examination must be repeated. 21 C.F.R. § 640.63(b).

C. *Hillsborough County Regulations.* In 1980, Hillsborough County, Florida ("County") promulgated two ordinances relating to plasmapheresis, and the County Department of Health ("Department") issued regulations thereunder. Ordinance 80-11 imposes a license tax, a public hearing process, requires the center to give "reasonable

and continuing access" to Department personnel for inspections, and to provide current information regarding personnel, equipment and facilities. (J.A. 21-23)

Ordinance 80-12 deals with donor registration. Its purpose is to provide a system for

> . . . registration and identification of and the gathering of medical data applicable to Commercial Blood Plasma Vendors as being in the common interests of the health of the people of Hillsborough County. (J.A. 24-25)

Ordinance 80-12 applies only to "commercial blood plasma vendors"—people who sell, barter or exchange their plasma (through plasmapheresis) for a monetary consideration. Ordinance 80-12 incorporates by reference the provisions of the Federal regulations relating *solely* to Source Plasma (Human), 21 C.F.R. Part 640, subpart G, §§ 640.60 *et seq.*, "as they may be amended from time to time." The key provisions of the County Scheme include:

—A donor registration requirement whereby a person is eligible to donate only after (i) being examined by a physician and obtaining a certificate of good health, (ii) obtaining (for $2.00 paid to the County) a registration card valid only for six months solely at one designated plasma facility, (iii) being free of hepatitis, as shown by test, and (iv) swearing an affidavit that he has not been "detained" or "treated" for acute or chronic alcoholism during the preceding 12 months. (J.A. 32)

—A fee of $1.00 for each plasmapheresis collection to be paid by the center to the County. (J.A. 27)

—A requirement that a donor take an alcohol breath-analysis prior to each collection of plasma. (J.A. 28)

—Annual inspection of the plasma center by the County. (J.A. 28)

—Delivery every day by the center to the County of detailed information about each plasmapheresis collection. (J.A. 29)

Ordinance 80-12 subjects plasma centers to criminal sanctions for violation of its provisions. (J.A. 31)

The County Scheme's requirements do not relieve the plasma center from complying with Federal regulations.[11] For example, while a County resident must have had a physical exam to obtain a donor registration card, a person possessing the requisite registration card must nevertheless be thoroughly examined by the plasma center physician pursuant to Federal regulations. And, although Federal regulations permit plasmapheresis of any healthy person, whether from the County or elsewhere, a center in the County cannot plasmapherese such a person unless he possesses a donor ID. Even if a registered donor is pretested for hepatitis under the County scheme, each unit of plasma must be tested and be "non-reactive" to hepatitis B-surface antigen under the Federal scheme. 21 C.F.R. § 640.67. Likewise, all the Federal donor suitability requirements for each donation must be complied with even though the donor has a County donor registration card.

D. *The Decision Below.* In a unanimous decision written by Chief Judge Tuttle, the Eleventh Circuit held that FDA's blood plasma regulations preempted all provisions of the County's scheme under the principles enunciated in *Pennsylvania* v. *Nelson*, 350 U.S. 497, 502-510 (1955). J.A. 48-59. The Court of Appeals found that the "pervasiveness" of the "comprehensive" federal regulatory scheme "makes it reasonable to infer that Congress left no room for local ordinances to supplement it." J.A. 55-57. Based on agency regulations reflecting a uniform National Blood Policy emphasizing an adequate, safe supply of blood and blood products, the court concluded that the field of plasma-

[11] Section 351's mandate is unlike the Clinical Laboratories Improvement Act of 1967, 21 U.S.C. § 263a, which permits exemption from federal licensing and inspection where the laboratory meets local requirements equal to or more stringent than the federal standards and which explicitly saves to the States the power to act "to the extent that such laws are not inconsistent with" the Federal act. 21 U.S.C. § 263a(k).

pheresis was one in which the federal interest was dominant over any state or local interest. J.A. 57-58. Finally, the court ruled that the requirements imposed by the County's ordinances were "burdensome and expensive" and would frustrate "the national blood policy of promoting uniformity and guaranteeing a continued supply of healthy donors." J.A. 58-59.

SUMMARY OF ARGUMENT

Whether federal law preempts local laws is a question of law to be determined by this Court. The Federal agency's view, therefore, is not dispositive but may be given weight and deference. Here, FDA's 1973 comment that its regulations were not intended to "usurp" local regulation of plasmapheresis related to a limited regulatory scheme. The regulations were subsequently broadened into a comprehensive, complete regulation of plasmapheresis, consistent with the National Blood Policy. The regulatory program itself evidences a stringent, thorough, complete approach to its subject matter. Thus, the Commissioner's 1973 statement cannot be dispositive of the question presented.

The Eleventh Circuit correctly applied the three tests of *Pennsylvania* v. *Nelson*, 350 U.S. 497 (1955).

(1) The comprehensiveness of the regulations is conceded by the United States. (U.S. Br. p. 7.) In any case, it is evident from an examination of the regulations themselves and the voluminous interpretive guidelines published by FDA. The County's regulations duplicate FDA's scheme and differ only in the methods selected to deal with specific aspects of plasmapheresis. Thus, the County scheme provides no protections not afforded by FDA's regulations and no real "local" interests, such as federalism traditionally recognizes, are served.

(2) The National Blood Policy declared the interest of the United States in a safe and adequate blood supply and

required that the full regulatory authority of the United States be applied to the practices of blood banking, including plasmapheresis. Progress toward achievement of the National Blood Policy has been scrutinized by Congress and its agencies. In any case the need for blood plasma and plasma products in the health care system establishes the national interest in the safety and efficacy of blood and blood products.

(3) The County scheme conflicts with the Federal regulations, particularly in the all important issue of donor suitability. The County scheme proceeds from a philosophical base different from that of FDA's regulations. FDA's regulations are premised on the twin concerns of product safety and efficacy *and* donor safety. In adopting the plasma regulations, the Commissioner took every reasonable step to assure donor safety and, at the same time, recognized his correlative duty to ensure that plasma donor suitability standards would not constitute a barrier to assuring an adequate source of supply for these vital products. 37 *Fed. Reg.* 17,420 (1972). By contrast, the County, purportedly exercising its police powers to protect the health of its residents, has adopted regulations that are concerned solely with donor safety, thus ignoring the national need to assure an adequate source of supply. This factor is the very heart of the conflict between the Federal regulations and the County scheme: FDA's regulations permit each and every healthy individual who meets specified criteria to donate plasma freely and of his or her own choice, while the County scheme allows an otherwise eligible donor to donate only if the County approves his doing so. FDA—and not the County—is competent to balance the needs of donor safety with the need to assure an adequate supply of plasma products. The County's burdensome and expensive requirements will frustrate the National Blood Policy's goals of uniformity in blood banking and plasmapheresis practices and will affect the adequacy of plasma supplies.

ARGUMENT

SINCE FDA'S COMPREHENSIVE PLASMA REGULATIONS IMPLEMENT A NATIONAL POLICY FAVORING UNIFORMITY AND ASSURING AN ADEQUATE PLASMA SUPPLY, THEY MUST PREEMPT LOCAL REGULATION WHICH CONFLICTS WITH OR FRUSTRATES THAT NATIONAL POLICY

A. "Preemption or No" is a Question of Law to Which FDA's 1973 Comment is Not Germane

This Court has held that whether federal law preempts a body of local law is a question of law. *Pacific Gas and Electric Co.* v. *State Energy Resources Conservation and Development Commission et al.*, 461 U.S. 190, 202 (1983). Accordingly, the Commissioner's 1973 statement that the regulations "are not intended to usurp" local authority to regulate plasmapheresisis, 38 *Fed. Reg.* 19,365 (1973), would normally be entitled to deference, but it is not dispositive of the question in this case.

Considered in isolation, this preamble statement might be evidence of the agency's views. Within months, however, the Commissioner was referring to "uniform high quality throughout the nation," "uniform and efficient enforcement of the law," 39 *Fed. Reg.* 18,615 (1974), "strict regulatory controls" and "comprehensive donor protection requirements," 39 *Fed. Reg.* 26,161 (1974), and later yet to "more stringent requirements than originally proposed," 41 *Fed. Reg.* 10,762 (1976). This change is not surprising, as the 1973 proposal was aimed only at procedures producing plasma for injectable products. 38 *Fed. Reg.* 19,362 (1973). Only a few months later, FDA realized that the goal of donor protection required that the regulations extend to all plasmapheresis procedures. 39 *Fed. Reg.* 26,161 (1974).

Moreover, after the Commissioner's 1973 comment, the Department of Health, Education and Welfare,[12] of which FDA is a part, participated in the development of the

[12] Now the Department of Health and Human Services. 20 U.S.C. § 3508.

National Blood Policy. That Policy articulated the goals of assuring an adequate supply of safe blood and blood products and employing "the *full regulatory authorities now vested* in the Federal Government . . . for the purpose of *assuring uniform adherence to the highest attainable standards* of practice in blood banking, *including plasmapheresis and plasma fractionation.*"[13] 39 *Fed. Reg.* 32,703 (1974) (emphasis added). Thus, it is not surprising that in 1973 the Commissioner might hesitate to "usurp" local authorities yet by 1974 be writing "comprehensive" and "stringent" regulations to result in products "of uniform high quality throughout the nation." The Commissioner also noted that, "The Supreme Court has reaffirmed that it is 'implicit in the regulatory scheme' for [FDA] to pursue a comprehensive, industry-wide program for a particular class of drugs 'for the achievement of the agency's ultimate purposes,' " citing *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 655 (1973). 39 *Fed. Reg.* 18,615 (1974).[14]

---

[13] Hillsborough County and the Solicitor General argue incorrectly that the National Blood Policy excluded the commercial plasmapheresis industry (County Br. p. 8; U.S. Br. p. 22). The National Blood Policy established the goal of an all volunteer supply for blood and blood products. But the National Blood Policy recognized that achieving this goal for acquisition of plasma was not practical "for the time being" because the volunteer community could not meet the demand for plasma. Accordingly the National Blood Policy excepted plasma from its all volunteer goal but in all other respects the National Blood Policy extended its requirements and goals—including that of "uniform adherence to the highest attainable standards"—to plasmapheresis. Similarly the argument that the National Blood Policy envisioned cooperative regulation by the states (County Br. pp. 8-9) misses the point. Any references to a possible role for state health departments are solely in the context of discussing regionalization of blood banking and transfusion services, 39 *Fed. Reg.* 32,707, 32,708 (1974), not plasmapheresis.

[14] Ironically, the very language cited by the County to show that the Commissioner recognized a dual system of regulation (" 'The Commissioner finds these programs are inadequate.' " County Br. p. 9 n.8) is how a federal agency would justify preempting local regulation, namely its inadequacy to accomplish the Federal goals, and was written after the March 1974 announcement of the National Blood Policy. 39 *Fed. Reg.* 18,614-15 (1974).

Nor is the Commissioner's 1973 pronouncement consistent with the FDA's regulatory approach, particularly since 1976. FDA has not regarded its authority as being limited to the formal promulgation of regulations and the inspection and licensing of facilities. Recognizing that medical knowledge is evolutionary, FDA publishes guidelines and interpretations on an as-needed basis. Over the years, the volume of these guidelines has been substantial. While these guidelines do not have the status of law, they are binding upon the agency in the sense that a person who acts in accordance with them is regarded as complying with Federal law. *See* 40 *Fed. Reg.* 40,695-6 (1975).[15] For example, in 1983, based largely on advice from ABRA and other blood industry organizations, FDA promulgated donor screening recommendations to prevent persons at high risk to AIDS from donating blood or plasma. These were recently updated.[16] A plasma center ignores these informal regulations at its peril.

In addition, a plasma center cannot be licensed without FDA approving its standard operating procedures manual ("SOP"). 21 C.F.R. Part 606. The SOP contains detailed information describing the procedures to which the center will adhere in all aspects of its operations, including donor suitability processing. These SOPs are lengthy, running several hundreds of pages, and complex. A center can be held in violation of law during an inspection if procedures specified in the SOP are not being followed.[17] Although the

---

[15] See also Allera, "FDA's Use of Guidelines, Notices of Proposed Rulemaking and Compliance Policies as De Facto Rules: An Abuse of Discretion, 3 *Plasma Quarterly* 76, 77, 89 (September 1981).

[16] Guidelines published from 1973 to the present, including the donor screening recommendations referred to, are lodged with the Clerk of this Court.

[17] There are probably about 100 different SOP's which have been approved by FDA in the licensure process, as well as a standard SOP prepared by ABRA (a copy of which is lodged with the Clerk of this Court). See 21 C.F.R. § 606; letter from FDA to ABRA lodged with the Clerk of this Court.

Solicitor General argues that "Congress did not intend to regulate wholly-intrastate activities," and therefore there is no intent to bar local governments from legislating in the plasmapheresis field (U.S. Br. pp. 16-17 and n.15), the United States elsewhere recognizes that plasmapheresis "is performed on a local basis," *Id.* at 17, n.16. Indeed, numerous portions of the SOPs approved by FDA relate primarily or solely to local activities, and the regulations themselves affect "wholly-intrastate" activities, *see* 39 *Fed. Reg.* 18,615 (1974). FDA in practice has not agreed that Congress did not intend to regulate intrastate activities.

B. The National Blood Policy's Requirement of "Uniformity," Which the Eleventh Circuit Found to Control Decision in This Case, Is Compelled by the Nature of the Industry and Federal Goals Relating Thereto

1. FDA's regulations and regulatory activities are consistent with FDA exercising a uniform, national exclusive jurisdiction and with the Court of Appeals conclusion that the "goal of uniformity runs throughout the regulations." J.A. 58. That this should be so follows logically from the very nature of the conflicting interests inherent in attempting to meet the National Blood Policy requirement that there be enough product to meet demand safely. On one hand, if there were no donor suitability standards, undoubtedly there would be more than enough plasma to meet demand but some of it would be from unhealthy donors or donors whose health would be threatened by intensive plasmapheresis. On the other hand, if plasma were required to be totally disease-free, the number of donors would be limited and there would be a dramatic shortage of plasma. Only a single agency charged with the responsibility to "insure the availability of good quality plasma," 39 *Fed. Reg.* 18,615 (1974), can undertake the balancing of interests required to *both* protect donor health and assure the availability of good quality plasma.[18] Clearly, Hillsborough County cannot do so.[19] By its own admission, it has no interest in doing so. Its only interest is in the health of its residents. (County Br. p. 10.) And this interest runs directly counter to the national interest in assuring an adequate supply of plasma. If every local jurisdiction were permitted to impose restrictions on plasmapheresis under the guise of exercising its police power, the national policy of assuring an adequate, safe supply of plasma products will be frustrated and the health care system will not have access to the plasma based products it needs.

Plasma products are not like cosmetics. Their users generally cannot consider price or select alternate products. Several years ago, for example, an industry leader estimated the annual cost for moderate to severe hemophiliacs to acquire AHF concentrate, and thus avoid crippling joint bleeds and pain relief not available from other therapies, at between $4,000 and $10,000 per year.[20] Any increase in cost wrought by local ordinances could have a disastrous effect on this group. Restrictions on paid plasmapheresis programs, in the opinion of a leading treater of hemophilia patients,[21]

---

[18] The balancing is reflected in comments by Dr. John Petricciani, present Director, Division of Blood and Blood Products, FDA, to a forum on plasmapheresis: ". . . the basic reason the Division even exists is to provide protection to the public. On the one hand the public isn't going to be protected if we take our responsibilities casually and are indiscriminately permissive in our regulatory activities . . . [o]n the other hand, I am just as firmly convinced that the public is not being well-served by inappropriate regulation . . . [t]he overall philosophy, then, is to try to balance those extremes, and to achieve a high level of protection for the public while not stifling research and product development." 7 *Plasma Quarterly* 126 (Winter 1985).

[19] The complexity of the scientific issues—to which the Federal regulations and FDA's guidelines are competent witness—suggest that the County would have to possess substantial scientific expertise to be able to do so.

[20] Randolph, "Plasma, Its Derivatives and Market," 1 *Plasma Quarterly* 74, 75 (September, 1979).

[21] Aledort, "The Availability of Plasma Products and the Care of Hemophilia Patients," 246 *J.A.M.A.* 157 (July 10, 1981). Aledort also points

> would be injurious to many patients in the United States and abroad. Restrictions would be particularly damaging to the United States hemophilia patients.

While not every action which would restrict plasma supply is inappropriate, the adverse impact of such actions should be weighed by an agency having the expertise and responsibility to do so.[22]

The need for uniformity, dictated by the National Blood Policy, is also supported by the fact that the plasma industry is generally not very profitable.[23] Testimony at trial showed that direct and indirect costs resulting from the County Scheme, coupled with an anticipated substantial decline in donors, would cause AML to operate at a loss.[24] If the County Scheme stands, other jurisdictions where

---

out that American hemophiliacs pay substantially less per unit of activity than the hemophiliac patients abroad. This is partly explained by the extensive plasmapheresis activity—both paid and voluntary—in the U.S.

[22] There are compelling reasons, such as concerns about AIDS, to risk distorting plasma and whole blood supply, even if the cost of the products will increase. Screening procedures designed to eliminate from the donor pool persons at risk to AIDS have led to a decline in the donor pool at both plasma centers and whole blood facilities.

The AIDS crisis illustrates the dominance of the federal interest in blood products in another way. The AIDS epidemic has brought a dramatic change in the way the American people perceive the blood banking community. *See e.g.*, "AIDS and the Growing Blood Scare," *Washington Post*, p. B1 (June 18, 1983). Hemophiliacs are asking whether they should continue prophylactic care with AHF concentrate. States are asking whether they should be taking action to regulate blood banking and plasmapheresis or related activities. It is a certainty that no two communities will see the problem the same. While a variety of regulatory initiatives are possible, such local responses are not the answer to AIDS-related concerns because they will restrict the blood and plasma supply without solving the underlying problem.

[23] Drake *et al.*, *The American Blood Supply*, M.I.T. Press, 1982, at 136. *See also Drake*, Table 6.6. at 73.

[24] Trial Transcript (Tr.), pp. 49, 51-2, 54-5, 81-2; PX 20, 21.

people decide they do not want plasma centers, *see* Plaintiff's Exhibit 14 (proceedings before the County Council), may adopt restrictive ordinances, and many plasma centers may face the same burdens and possibly unprofitable operations.[25] The inevitable result must be a reduction in plasma supplies and a concomitant increase in the price of plasma products. These costs will become part of the spiraling rise in health care costs. OTA, *supra*, at 8, 17.

At trial, Appellee estimated the cost impact of the County's regulations as being more than about $7.00 per liter in additional costs, including an estimated decline in the donor population, but not including the additional cost of an independent physical examination and other donor registration costs.[26] Industry is aware of other cost push factors, of which Hillsborough County may not be aware and in any case has no responsibility to consider.[27] The

---

[25] For example, Pima County, Arizona proposed similar local regulation of plasma centers, but withdrew its proposed ordinance when the Eleventh Circuit decision was published. A bill recently introduced in the Texas legislature would ban plasmapheresis of any person not holding a driver's license or a certificate issued by the Texas Department of Public Health. Texas HB No. 1102 (Feb. 22, 1985) (lodged with the Clerk of the Court). Other jurisdictions have tried to regulate plasmapheresis, or ban the purchase of blood and plasma from donors, *see State of Wisconsin* v. *Interstate Blood Banking, Inc.*, 65 Wis.2d 482, 222 N.W.2d 912 (1974), and others have seriously restricted or banned plasma center operation through the application of zoning laws.

[26] *See* Tr. at 51. A physical examination comparable to that required by FDA could be $75.00 or more. At the present time, fractionators are paying approximately $55.00 for a liter of plasma and obtaining products with a total sales value of about $89.00. Thus, the fractionator has only $34.00 to cover manufacturing, marketing, all overhead, research and development, as well as profit and taxes. Any amount added to the raw material cost will ultimately be added to finished product prices.

[27] These include use of a test for the antibody to the virus thought to cause AIDS, increased manufacturing costs resulting from use of a heat treatment process developed to make coagulation products safer, and a dramatic rise in price of "recovered plasma," caused by short supply of source plasma. Recovered plasma, salvaged from whole blood toward the end of its shelf life, has less value as manufacturing raw material than source plasma.

combination of local regulation with these market forces and the requirements of FDA is obviously significant. As prices go up and plasma is harder to obtain, the burdens of local regulation become a more important factor in the conduct of business.[28]

The Government has conceded (U.S. Br. p. 8) that FDA "may some day decide to preempt such local regulations" if their "widespread adoption threatens to hamper" FDA's ability to assure the existence of an adequate supply of blood plasma. This implies that the nation would have to experience a shortage of plasma products before FDA would react to the patchwork of restrictive local regulation that could be so harmful to the nation's blood and plasma supply.[29] To wait until some user of plasma products, such as a hemophiliac, experiences the inability to buy the product because it is in short supply is irresponsible, contrary to the National Blood Policy, and contrary to the Commissioner's statutory duties.

The Commissioner's 1973 statement, then, is not dispositive of this case and long since has ceased being an accurate statement of FDA's position. In light of later developments, it should not even be accorded any weight in the legal determination to be made by this Court whether FDA's comprehensive scheme now preempts the County's limited, but conflicting rules.[30]

---

[28] *See* OTA, supra, at 68; Grossman and Schmitt, "The Plasma Derivative Market: An Overview," prepared for the U.S. Congress Office of Technology Assessment, Contract No. 433-5650, p. 39.

[29] Just as product liability laws have caused manufacturers of certain vaccines to withdraw from the market (*See* "Product Liability: The New Morass," *New York Times*, Section 3, p. 1 (March 10, 1985)), local regulation can cause plasma centers to withdraw from the market. In 1972, at the time Dade County passed an ordinance similar to Hillsborough County ordinances, there were eleven plasma centers. Today there are two.

[30] As shown, FDA abandoned its 1973 position almost immediately after enunciating it. Because of this shift in regulatory positions, there is no reason to defer to the Commissioner's 1973 statement, for "[i]t is enough

C. The Eleventh Circuit Decision, Based on *Pennsylvania* v. *Nelson*, Correctly Found That the Local Scheme Is Preempted

The National Blood Policy's emphasis on uniformity and assuring an adequate supply of blood and blood products is no accident. Its architects recognized the relationship between regulatory uniformity and the need to balance competing policy goals to achieve both donor safety and an adequate supply. The County's regulations do not recognize that relationship and risk disrupting an industry that serves the vital needs of the American health care community.

Analysis begins with the two statutes on which FDA's regulations are based.[31] PHS Act Section 351 expresses Congress' intent that the federal regulation of biological products was a subject so imbued with the national interest that a strong scheme of federal regulation should be imposed. In pertinent part, Section 351 provides:

---

to say that [the agency's positions] have not been uniform and do not establish any settled interpretation that is applicable here." *United States* v. *Missouri Pac. R.R.*, 278 U.S. 269, 282 (1929). Moreover, this Court ought not to accord deference to the position advanced here for the first time in this litigation by counsel for the United States that FDA's regulations do not preempt the County scheme. It is well-established that reviewing courts must accord deference only to positions actually relied upon by an administrative agency, and not those simply advanced by counsel in litigation. *E.g., American Textile Mfrs. Inst.* v. *Donovan*, 452 U.S. 490, 539 (1981); *SEC* v. *Chenery Corp.*, 318 U.S. 80, 94-95 (1943). In face of the National Blood Policy, upon which *amici's* members have relied, FDA's decision to abrogate the National Blood Policy's interest in uniformity by not preempting local regulations should, at a minimum, not be accorded substantial deference by the courts until it has been considered in a process which parallels that by which the National Blood Policy was developed, involving all the concerned parties, including Congress.

[31] Not contested in this case are three significant propositions: first, FDA's regulations are within its statutory authority. (U.S. Br. p. 7) Second, FDA has full authority to issue regulations which have a preemptive effect. (U.S. Br. p. 18) Third, these regulations are comprehensive. (County Br. p. 10)

> (a) *No person* shall *sell,* . . . any . . . blood, blood component, or derivative . . . *unless* (1) such . . . blood, blood component or derivative . . . *has been propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license, issued by the Secretary.* . . .
>
> (d) *Licenses for* the maintenance of *establishments . . . may be issued only upon a showing that the establishment and the products . . . meet standards,* designed to insure the continued safety, purity and potency of such products, *prescribed in regulations, . . . All such licenses shall be issued, suspended, and revoked as prescribed by regulations.* . . .

42 U.S.C. § 262 (emphasis added). The statute's very restrictive terms permit the inference that Congress intended to comprehensively and completely regulate blood and derivatives and to bar any standards that differed from the Federal standards.[32] The so-called "new drug" section of the FDC Act, 21 U.S.C. § 355,[33] has the same structure as Section 351 and can be similarly interpreted. See also *National Women's Health Network, Inc.* v. *A.H. Robins Company, Inc.,* 545 F. Supp. 1177 (D. Mass. 1982) (FDC Act would preempt state law "recall theory"). But even if the statutes alone do not require preemption, FDA's comprehensive regulations clearly do.

Pennsylvania v. *Nelson,* 350 U.S. 497 (1955), requires that three questions be analyzed. First, is the regulatory scheme so comprehensive that it is reasonable to assume that Congress left no room for local supplementation? *Id.* at 502. Second, is the federal interest in the subject

[32] See *Armour and Company* v. *Ball,* 468 F.2d 76 (6th Cir. 1972). The statutory language considered in *Armour* was not unambiguously preemptive, as the law there at issue permitted state action "consistent" with the Federal law as to "matters regulated" under the Federal Act. Nonetheless, the Sixth Circuit concluded that all but identical state standards were preempted.

[33] Biological products are also drugs subject to provisions of FDC Act. *See, e.g.,* 37 *Fed. Reg.* 17,419 (1972).

matter so dominant that the federal system must be assumed to preclude enforcement of state laws on the same subject? *Id.* at 504. Third, does the local ordinance conflict with the federal regulation or will its enforcement frustrate national interests? *Id.* at 505. In this case, all three questions must be answered "yes."

1. That FDA's regulations are comprehensive is conceded by the Solicitor General (U.S. Br. p. 7) and by the County. County Br. p. 10. Federal regulations cover every aspect of plasmapheresis, including donor safety.[34] Each of the purported "additional protections" provided by the County scheme[35] is, in fact, nothing more than a different technique for dealing with a concern already addressed by FDA. "Vendor registration," for example, is an attempt to prevent overbleeding but the Commissioner was aware of the problem and addressed it adequately. That the County disagrees with a means chosen by the federal agency having expertise does not demonstrate that the federal regulations do not preempt local action on the same subject matter.

This is especially so where the available evidence suggests that the means required by the Federal regulations does accomplish the intended purposes. As shown in a study of 6,271 first time donors during the period between January 1, 1978 and March 1, 1978 and a total of 30,214 donations by these donors, there were 1,813 rejections or deferrals resulting from: lab tests and the donor screening process (59.7%), donor history (25.1%), and the balance

[34] If the regulations themselves are not "comprehensive," the guidelines and interpretations and the approved center SOP fill the gaps.

[35] The United States, the local government *amici* and the County characterize FDA's regulations as "minimum" standards. There is no authority for that characterization in the *Federal Register* preambles or in the regulations themselves. To the contrary, the Commissioner describes the standards as "uniform", 39 *Fed. Reg.* 26,161, 26,162 (1974), "comprehensive", *ibid.*, "specific", 37 *Fed. Reg.* 17,419, 17,420 (1972), designed to assure "high quality throughout the nation," 39 *Fed. Reg.* 26,165 (1974).

from donor behavior. Approximately 97 rejections resulted from the donor being observed to be under the influence of alcohol and 18 because of needlemarks. 278 rejections were based on the donor returning too soon following a previous plasmapheresis. Significantly, 41 donors were rejected because of suspected "cross-donating," or giving plasma at another center.[36]

The County's assertion that FDA regulations do not protect against multi-center over-bleeding demonstrates the County's lack of understanding of the very Federal regulations which it claims the right to enforce. The regulations require that each potential donor be asked about his last plasmapheresis session and that the answer be recorded, that the phlebotomist examine both arms for evidence of venipuncture (also useful in screening out intravenous drug users), and that the donor's hematocrit and total protein be tested and recorded. 21 C.F.R. 640.63. These tests will indicate whether the donor has subjected himself to overbleeding. 38 *Fed. Reg.* 19,364 (1973).

Each of the other "additional protections" found in the County scheme are of the same character: a subject covered by FDA but not to the satisfaction of the County.[37] The

[36] Reasor, "Rejection and Attrition of Compensated Plasmapheresis Donors," 1 *Plasma Quarterly* 72, 71-88 (Sept. 1979) (hereinafter cited as "Reasor"). There was no evidence presented at trial that the Federal regulations are not adequate to prevent cross-donating. Indeed, at trial, there was no evidence of *actual* instances of "cross-donating," only suspicions that this might be a problem. See Tr. 63.

[37] The Federal provision on physician examinations is 21 C.F.R. § 640.63 (b); on alcohol breath-analysis, 21 C.F.R. § 640.69(d); on inspection, 21 C.F.R. § 640.69(c); and on record keeping, 21 C.F.R. § 640.72.

The County justifies its requirement on breath-analysis by claiming it will assure that the donor gives "truly informed consent" and by referring to newspaper reports of a hemolytic reaction incident. (County Br. p. 18 n.21). The first of the articles cited shows that there was a mixup by center workers, not a problem with an uninformed or intoxicated donor. Informed consent, re-infusion procedures, and hemolytic reactions are all described in the Federal regulations and in approved SOPs including

County attempts to evade this truth by arguing that the dominant federal interest is to "insure a safe and plentiful product in interstate commerce" (County Br. p. 10 n.13), not in donor safety. This contention is simply unfounded in face of the Commissioner's statements that, for example, he was including "specific provisions designed to protect the health and well-being of the donor," 37 *Fed. Reg.* 17,419, 17,420 (1972), and protection of plasma donors was "one of the major purposes of the regulations." 41 *Fed. Reg.* 10,762-3 (1976).[38]

2. The Commissioner himself recognized that the National Blood Policy was "comprehensive" and that one of the "methods . . . to implement the policy" was employment of "the full regulatory authorities now vested in the federal government . . . for the purpose of assuring uniform adherence to the highest attainable standards of practice in blood banking, including plasmapheresis and plasma fractionation." 39 *Fed. Reg.* 32,703 (1974) (quoting from 39 *Fed. Reg.* 9,329-30). The statements of the National Blood Policy itself are not equivocal on the importance of the federal interest.[39]

Congress periodically reviews the status of the National Blood Policy. In 1979, then Senator Schweiker held hear-

ABRA's Industry Manual. It is unfortunate but not surprising that an industry that performs 10,000,000 procedures annually has mistakes on rare occasions. The County requirement that donors be free of hepatitis largely duplicates FDA's regulations, which require that every unit must be tested, positive units be destroyed and positive donors be rejected. 21 C.F.R. §§ 640.63 (c)(11), 640.67.

[38] It is significant that the County's scheme does not address the two issues that give rise to "the greatest controversy" regarding donor safety—limitations on the volume and frequency of donation. OTA, *supra*, at 40. The County's claim to have supplemented FDA's regulations is hollow indeed.

[39] This Court has held that the FDC Act should be given a liberal construction consistent with its overriding purpose to protect the public health. *U.S.* v. *An Article of Drug, . . . Bacto-Unidisc,* 394 U.S. 784, 798 (1960).

ings regarding the voluntary sector's progress toward the goals of the National Blood Policy. Hearing, June 7, 1979, before Subcommittee on Health & Scientific Research of Committee on Labor & Human Resources, U.S. Senate, G.P.O., 1979. In 1983, in response to concerns about the blood supply, Congressman Dingell asked the Office of Technology Assessment to study the entire field of blood and blood products for possible congressional action. OTA's study, recently released, concluded that the nation's blood supply, including the supply of plasma products, is safer than ever before. OTA, *supra* at 37. As the report reveals, Federal involvement in the blood field is far more extensive than just FDA's regulatory efforts and includes, for example, reimbursement through Medicare for blood and blood products. *See* OTA, *supra* at 41-48.

Thus, blood and plasma are not a subject matter like avocados, which this Court deemed "an inherently unlikely candidate for exclusive federal regulation." *Florida Lime and Avocado Growers, Inc.* v. *Paul,* 373 U.S. 132, 143 (1963).[40] Rather, plasma is a subject more like tamper-resistant packaging where FDA exercised authority under the FDC Act to preempt state regulation of packaging. FDA recognized that over the counter (OTC) drugs are part of national commerce, and that local requirements would interfere with Federal objectives and the distribution of OTC drugs. FDA also balanced the need for protection with the potential burdens and costs. *See* 47 *Fed. Reg.* 50,442, 50,443, 50,447-8 (1982).[41]

Moreover, the County is unable to point to any particular "local needs" (U.S. Br. p. 12) not addressed in the Federal

[40] *Florida Lime* was a case where "Congressional superintendence of the field" was "partial", 373 U.S. at 145, not "comprehensive" and total, as here.

[41] See also FDA's regulations on a warning to pregnant or nursing women on OTC drugs, recognizing the national interest in a uniform warning and the confusion that differing local requirements would engender. 47 *Fed. Reg.* 54,750, 54,756 (1982).

regulations, any circumstances that suggest the County is different from other jurisdictions as respects plasma donors, or any factor that suggests that its citizens need more protection than those recognized by FDA as needing protection, 39 *Fed. Reg.* 26,161 (1974), from "exploitation," *Id.* at 26,162. Characterizing the County's interest as being the strong "traditional interest [of a local government] in protecting the health of [its] citizens" (U.S. Br. p. 25) is not sufficient to prevent Federal law from acting exclusively to regulate such subject matter. *Fidelity Federal Savings & Loan Association* v. *De la Cuesta,* 458 U.S. 141 (1982).

3. As this Court said in *Michigan Canners & Freezers Association, Inc.* v. *Agricultural Marketing and Bargaining Board,* 104 S.Ct. 2518, 2523:

> even in the absence of express preemptive language, Congress may indicate an intent to occupy an entire field of regulation, in which case the State must leave all regulatory activity in that area to the Federal Government, e.g. *Fidelity Federal Savings & Loan Ass'n* v. *de la Cuesta,* 458 U.S. 141, 153 (1982); *Rice* v. *Santa Fe Elevator Corp.,* 331 U.S. 218, 230 (1947). Finally, if Congress has not displaced state regulation entirely, it may nonetheless preempt state law to the extent that the law actually conflicts with federal law. Such a conflict arises when compliance with both state and federal law is impossible, *Florida Lime & Avocado Growers, Inc.* v. *Paul,* 373 U.S. 132, 142-143 (1963), or when the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines* v. *Davidowitz,* 312 U.S. 52, 67 (1941). See also *Fidelity Federal S&L, supra,* at 153.

National policy recognizes two goals that are, as described above, competing: assuring an adequate supply of blood and blood products and protecting the donor. Because the reconciliation of these national goals requires a balancing, local regulation which differs from FDA's scheme and which serves only one of the goals, that of donor health,

will inevitably stand "as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines* v. *Davidowitz*, 312 U.S. at 67, by both creating conflicts and frustrating the uniformity so essential to the "purposes and objectives of Congress."[42]

The Eleventh Circuit found that the County scheme "imposes burdensome and expensive requirements in addition to the requirements of the comprehensive federal scheme." J.A. 59. Plasma centers in the County now have two sets of rules to play by. For example, FDA's recent reduction of the frequency of mandatory inspections based on an establishment's compliance history, 48 *Fed. Reg.* 26,314 (1983), is effectively reversed by the County Scheme, even for a plasma center which has worked diligently to establish a record of high compliance. And it is possible that County inspectors, applying both Federal and County standards, will apply different standards in practice from Federal inspectors, creating compliance problems and conflicts.[43]

Daily reporting of *routine* information, an unusual requirement, is a very tangible burden of the County scheme. The information required to be forwarded daily to the

[42] There is some evidence that Hillsborough County (like other jurisdictions which have considered some form of regulation of plasmapheresis) was not concerned solely with the health of its residents. A perceived social problem of vagrancy and public inebriation is implicit in minutes of meetings of the County commissioners (see Plaintiff's Trial Exhibits 8 and 14), and correspondence of a County official showed his full awareness that the proposed regulation could put plasma centers out of business. (Plaintiff's Trial Exhibits 6 and 7). There is no suggestion, however, that Hillsborough County is willing to forego the availability of plasma products to treat, for example, its hemophilia patients or burn patients.

[43] As another example, under the provision permitting variances, 21 C.F.R. § 640.75, FDA guidelines now allow plasma centers to use "adequately trained physician substitutes" to perform some physician functions. The County scheme may not recognize this or other variances. See FDA Memorandum re "Physician Substitutes" (Dec. 14, 1984) lodged with the Clerk of this Court.

County (along with $1 per plasmapheresis session) is duplicated in records that must be kept until after the product expiration date. 21 C.F.R. § 606.160(d). Unless carefully monitored by persons equipped by training and experience to understand the data, these records are not meaningful on a daily basis. Rather, they take on significance in inspection and review of the records of a facility over a span of time, or for review in the case of an adverse reaction.[44]

In addition to these "burdensome and expensive" requirements, the County scheme contains other direct conflicts with the Federal regulations. Under Federal law, any person judged in good health and meeting certain specified test parameters is permitted to undergo plasmapheresis. By contrast, under the County scheme only persons who have been registered by the County can undergo plasmapheresis. The County system prohibits an otherwise eligible, healthy donor from being processed in accordance with Federal law and the center's SOP. Under the County scheme, the plasma center must turn that person away until he or she obtains a registration card. Obtaining the card will require time—perhaps a few days—and the expense of the physical examination, which may be given by doctors who are unfamiliar with plasmapheresis.

[44] There is also a direct conflict between FDA's regulations and the Ordinances concerning the sensitive issue of the confidentiality of personal health information provided by blood donors. Under FDA's regulations, donor health records are created and maintained by the collection facility itself, rather than by FDA, 21 C.F.R. § 600.12, and would not be subject to the federal disclosure provisions of the Freedom of Information Act, 5 U.S.C. Section 552a, or the exceptions to the Federal Privacy Act. *Forsham* v. *Harris*, 445 U.S. 169, 182 (1980). By contrast, the Ordinances specifically permit disclosure of the information submitted daily by the Health Department if "such disclosure is directly related to and necessary for enforcement of this Ordinance or as is required by law." Ordinance 80-12, § 6(E). This more permissive approach would undoubtedly have a chilling effect upon willingness of potential donors to donate plasma and to be candid in revealing details of their medical history.

Hepatitis plasma is but an example of the conflict created by the donor registration scheme.[45] There are numerous "disease" plasmas which can be drawn under Federal law if a license is obtained. Donors who are sources of "disease" plasma may have a short-term illness, and therefore, have an antigen, antibody or other protein substance of medical value for only a short time. If a plasma center cannot access such persons quickly, the desired protein may disappear. FDA recognized that many such persons can be safely plasmapheresed and has developed licensing procedures to accommodate these special needs. A local registration requirement and evaluation by physicians lacking experience is, however, likely to delay the plasmapheresis of these persons beyond the useful period for doing so.

The County scheme thus frustrates the implementation of national policy by standing "as an obstacle to congressional purpose and objectives." *Capital Cities Cable, Inc.* v. *Crisp*, 104 S.Ct. 2694 (1984). First, the goal of assuring a "continuous and healthy donor population" will be frustrated because the burdens imposed by the County's regulations will diminish the number of persons ready and willing to provide their plasma.[46] Second, the decline in donor population and the increased costs flowing from the County scheme will threaten the assurance of an adequate supply of plasma products. Third, the goal of uniformity in both the regulatory environment and in quality of plasma products will be frustrated in that there will be—inevitably—a patchwork of regulatory standards for plasmapheresis (and bloodbanking). Each of the major fractionators operates many centers. For them, a regulatory patchwork is not just an inconvenience; it poses operating, training, and quality control problems. Plasma—and blood—is too complex and too important to be subject to the regulatory thought processes of hundreds of municipal officials.

[45] The County's claim that this conflict is "illusory" is confusing. (County Br. p. 15). Persons whose plasma is useful for production of hepatitis vaccine are persons who have been exposed to hepatitis and whose plasma contains Hepatitis B antigen. These persons will test positive and will be unable to receive a donor card. Thus, the donor registration requirement will effectively prevent a center from collecting hepatitis plasma.

[46] There was proof at trial that the donor population at AML would decrease significantly as a result of the Ordinances. Though the District Court found it speculative, the Court of Appeals was not, apparently, troubled by that. J.A. 59. *Cf. Dixie Dairy Co.* v. *City of Chicago*, 538 F.2d 1303 (7th Cir. 1976) (speculative evidence may be a necessary part of proving the burdens that flow from dual regulation).

CONCLUSION

"Human blood is a priceless resource." 39 *Fed. Reg.* 18,614 (1974). The National Blood Policy and statements of FDA's Commissioner and of other representatives of the Federal Government testify to the importance national policy attaches to blood and blood products. This interest, which mandates uniformity in regulatory activities to accomplish the goal of assuring an adequate supply of safe blood and plasma derivatives, overrides the interests of local jurisdictions in regulating activities already thoroughly and adequately regulated by FDA. For these reasons, the Eleventh Circuit properly held the County scheme preempted by FDA's regulations. This Court should affirm that decision.

Respectfully submitted,

RICHARD LANDFIELD
Counsel of Record
WILLIAM W. BECKER
LANDFIELD, BECKER & GREEN
1220 Nineteenth Street, N.W.
Suite 201
Washington, D.C. 20036
(202) 775-0300

Counsel for the Amici Curiae

APPENDIX

APPENDIX A

CODE OF ETHICS
of
American Blood Resources Association

Code of Ethics

IT SHALL BE THE HOPE, PROMISE, AND THE DUTY OF MEMBERS OF THE AMERICAN BLOOD RESOURCES ASSOCIATION

1. To INSURE an adequate and safe supply of blood and blood derivatives for medical, pharmaceutical, and scientific use.
2. To MAINTAIN the highest professional standards in their facilities.
3. To UTILIZE modern tested collection methods to insure maximum donor safety.
4. To INFORM the public of the need for and uses of blood and blood derivatives.
5. To ENCOURAGE the public to participate in blood derivative programs.
6. To FOSTER research and development in all areas of blood and blood derivative utilization.
7. To COOPERATE with all levels of government initiating programs affecting blood and blood derivative collection, utilization, and safety.
8. To PROMOTE and maintain cordial and unselfish relationships with members of their own profession and of other professions for the exchange of information concerning the utilization and preparation of blood and its products to the advantage of mankind.
9. To RECOGNIZE that the ultimate purpose of the membership is service to the patient.

No. 83-1925

IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

HILLSBOROUGH COUNTY, FLORIDA, *et al.*,
Appellants,

v.

AUTOMATED MEDICAL LABORATORIES, INC.

On Appeal from the United States Court of Appeals for the Eleventh Circuit

BRIEF FOR GROCERY MANUFACTURERS OF AMERICA, INC. AS AMICUS CURIAE IN SUPPORT OF APPELLEE

PETER BARTON HUTT
Counsel of Record
Covington & Burling
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20044
(202) 662-5522

STEPHEN A. BROWN
Grocery Manufacturers of America, Inc.
Suite 800
1010 Wisconsin Avenue, N.W.
Washington, D.C. 20007
(202) 337-9400

Counsel for Amicus Curiae

March 29, 1985

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Table of Authorities Continued

Table of Authorities Continued

Table of Authorities Continued

Table of Authorities Continued

Table of Authorities Continued

IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

No. 83-1925

HILLSBOROUGH COUNTY, FLORIDA, *et al.*,
Appellants,

v.

AUTOMATED MEDICAL LABORATORIES, INC.

On Appeal from
the United States Court of Appeals
for the Eleventh Circuit

BRIEF FOR GROCERY MANUFACTURERS OF AMERICA, INC. AS AMICUS CURIAE IN SUPPORT OF APPELLEE

INTEREST OF AMICUS CURIAE

The Grocery Manufacturers of America, Inc., is a trade association representing companies that manufacture food and other grocery products for nationwide distribution. Its members include the principal grocery manufacturers in this country. Members of the association ship products in interstate commerce for sale throughout the country and are subjected

both to federal regulatory requirements and to numerous different or additional regulatory requirements imposed by various state, county, and local governments. The association and its members therefore have a major interest in assuring that regulatory requirements imposed on all food and drugs, including blood and blood products, are uniform across the country in order to facilitate nationwide production and marketing without restrictive trade barriers. The association and its members strongly support concurrent jurisdiction of state, county, and local governments to enforce uniform national standards identical with federal requirements, but oppose additional or different requirements on a local level that impede commerce for no public health benefit.[1]

SUMMARY OF ARGUMENT

Congress has authorized comprehensive federal regulation of all aspects of blood and blood products — from donation of blood, through processing and storage, to ultimate use — under three separate statutes: (1) the Biologics Act of 1902[2], which was recodified as part of the Public Health Service Act of 1944[3] and subsequently amended to confirm the inclusion of blood products[4], (2) the Federal Food, Drug, and Cosmetic Act of 1938[5], as subsequently amended by the Drug Amendments of 1962[6] and the Drug Listing Act of 1972[7] to provide additional regulatory authority, and (3) the communicable disease prevention provisions in section 361(a) of the Public Health Service Act.[8] No aspect of the collection, processing, marketing, and

[1]All parties have consented to the filing of this brief by letters that have been filed with the Clerk of the Court in accordance with Rule 36.

[2]32 Stat. 728 (1902).

[3]58 Stat. 682, 702 (1944), 42 U.S.C. § 262.

[4]84 Stat. 1297, 1308 (1970).

[5]52 Stat. 1040 (1938), 21 U.S.C. § 301 *et seq.*

[6]76 Stat. 780 (1962).

[7]86 Stat. 559 (1972).

[8]58 Stat. 682, 703 (1944), 42 U.S.C. § 264(a).

use of blood remains unregulated under these pervasive federal statutory authorities.

Blood is a relatively recent article of commerce. As more has become known about it through the advancement of the biological sciences, federal regulation has become increasingly more detailed and stringent. Federal regulatory efforts culminated in the development in 1973 of a National Blood Policy, which explicitly stated that it is "the policy of the United States Government:"

> "(7) To employ the full regulatory authorities now invested in the Federal Government and to seek such additional authority as may be necessary and appropriate for the purpose of assuring uniform adherence to the highest attainable standards of practice in blood banking, including plasmapheresis and plasma fractionation."[9]

Pursuant to this National Blood Policy, the Food and Drug Administration (FDA) has used the statutory authority cited above to promulgate an extraordinary number of implementing regulations governing all aspects of blood banking, including plasmapheresis and plasma fractionation. As a result of these federal regulatory efforts, there is no conceivable gap in public protection relating to blood and blood products, and no public health justification for different or additional state, county, or local requirements that are not identical to the federal requirements.

In defiance of the National Blood Policy and the comprehensive and detailed federal regulations implementing it, Hillsborough County has imposed its own additional and different regulatory requirements. Instead of enforcing requirements identical to those under federal law, Hillsborough County has chosen to enforce different requirements. If Hillsborough County can constitutionally enforce different and additional requirements, not identical to the federal requirements, then

[9]39 Fed. Reg. 9326, 9329-9330 (March 8, 1974); 39 Fed. Reg. 32702, 32703 (September 10, 1974).

every state, county, and local government in the United States has equal constitutional power to do so. Such a result would frustrate the purpose of the National Blood Policy and implementing federal regulations and would represent the very balkanization of commerce in blood and blood products sought to be prevented by the Commerce Clause of the Constitution.

The problem raised by this case is illustrative of the general lack of national uniformity in the regulation of all food and drugs in the United States. Today there is one nationwide market for food and drugs. Recognizing this fact, Congress has enacted a remarkable array of regulatory statutes, and FDA has implemented them with comprehensive and detailed regulations, to govern every aspect of these products from production to use. But just as this case reveals in the specific example of blood and blood products, contrary to the congressional intent of a unified national regulatory system there are different and additional laws and regulations for food and drugs on the state, county, and local levels of government, for no public health reason.

This problem has historical origins. In the early days of this country, food and drugs were consumed where they were grown.[10] As cities began to develop, local food markets were established to fill the need. Town ordinances were adopted to regulate the food supply sold in those markets. As cities grew larger, and food and drug distribution expanded, county laws were established to regulate them as well. By the mid-1800s, states were also enacting regulatory laws in this area. Because the production and distribution of food and drugs were still primarily local or regional matters throughout the 1800s, however, there was no federal law establishing a nationwide regulatory policy for these articles of commerce until after 1900.

---

[10]Even through the end of the 19th century, most drug products were natural botanicals and the same herbs and other natural products were often used for both food and drug purposes.

Shortly after 1900, Congress enacted the first nationwide food and drug laws. Because of this Court's narrow interpretation of the Commerce Clause at that time, however, these statutes were very limited in their jurisdiction. Food and drugs were not covered if they were produced and distributed locally. Nor were they covered after their shipment in interstate commerce. It is not surprising, therefore, that Supreme Court decisions during the early 1900s ruled that these federal laws did not preclude different requirements in state and local laws.

These early federal laws were subsequently replaced by more modern laws that now pervasively regulate every aspect of food and drugs. These federal laws, and the detailed regulations promulgated by FDA to implement them, reflect a clear federal intent to occupy this field. By the time these modern laws were enacted, however, it was too late for them to serve as a model for state and local legislation or to make enactment of state and local legislation unnecessary in this area. Different and additional state and local laws regulating food and drugs were already well-established and have continued to this day.

Beginning with the development of a significant nationwide commerce in food and drugs, and the resulting efforts to enact federal legislation to assure consumer protection with respect to these products, concurrent attempts were made to achieve uniformity between the federal requirements and the state and local requirements, through informal means of persuading state and local governments to adopt laws and regulations uniform with the federal laws and regulations. The Association of Analytical Chemists, the Association of Food and Drug Officials, various governmental agencies and organizations, and others have continuously encouraged the principle of national uniformity for at least the past 100 years, but without success. Notwithstanding the intent of Congress to enact a comprehensive national regulatory scheme, the country is no closer to national uniformity in the regulation of food and drugs today than it was in the late 1800s. The efforts at achieving uniformity through informal persuasion have repeatedly failed and will continue to fail in the future.

The net result is that the country continues to suffer from nonuniform state and local laws and regulations governing the production and marketing of food and drugs, including blood and blood products. There is no incentive for state and local governments to adopt a uniform national regulatory policy, and no statutory penalty if they fail to do so. The only effective limit on state and local action is the Commerce Clause of the Constitution. It is thus imperative that this Court establish general principles under the Commerce Clause that will preclude continuation of the present patchwork of laws and regulations throughout the country, and instead require national uniformity in the best interests of the country.

The federal government has a preeminent interest in assuring uniformity of food and drug regulation. To accomplish that purpose, Congress and FDA have established a pervasive system of federal regulation of food and drugs that leaves no room for supplementation by state and local governments. A crucial role remains for state and local regulatory authorities in the enforcement of uniform requirements established under the leadership of the federal government.

ARGUMENT

I. Laws Regulating Food and Drugs Were Initially Enacted by State and Local Governments Before the United States Became One National Market-Place, But Have Been Superseded by Comprehensive Modern Federal Statutes and Regulations.

A. The Growth of State and Local Laws in the 1800s

Colonial America was an agrarian economy. People consumed the food and herbal drugs they produced. Even those who lived in small towns kept livestock and their own gardens.

As urban centers began to develop, local food markets were established to serve them. In his classic study, De Voe traced the history of the public markets of the City of New York from

the origin of the West India Company's store in the 1630s through the 1840s.[11] As these markets were established, the City of New York adopted various regulatory requirements to control them. These requirements largely reflected the English common and statutory law.

Although many of these early laws were directed to specific commodities or problems[12], a number were directed more generally at preventing any form of adulteration.[13] As cities grew larger, concern about public health expanded. Beginning in 1820, a series of publications in England and the United States documented adulteration of the food and drug supply, and its consequences to both the public pocketbook and the public health.[14] Lemuel Shattuck's landmark report on public health in 1850 documented the decrease in average life expectancy at birth in America's large urban centers and identified the adulteration of food and drugs as a matter of public health concern.[15] Shattuck recommended the establishment of local boards of health which would "endeavor to prevent the sale and use of unwholesome, spurious, and adulterated articles, dangerous to the public health, designed for food, drink, or medicine."[16]

Five years after his earlier book, De Voe published another study in which he noted the great expansion in public trade and

---

[11] T.F. De Voe, *The Market Book: A History of the Public Markets of the City of New York* (1862).

[12] *E.g.*, *The General Laws and Liberties of the Massachusetts Colony* 17 (beef and pork), 53 (fish), and 54 (fish) (1672 ed.). *See generally*, W. Janssen, *America's First Food and Drug Laws*, 30 Food Drug Cosm. L.J. 665 (1975).

[13] In 1785, Massachusetts enacted "An Act against selling unwholesome Provisions," which is reproduced in 31 Food Drug Cosm. L.J. 246 (1976).

[14] *E.g.*, F. Accum, *A Treatise on Adulterations of Food and Culinary Poisons* (1820); L.C. Beck, *Adulterations of Various Substances Used in Medicine and the Arts* (1846).

[15] L. Shattuck, *Report of the Sanitary Commission of Massachusetts* (1850).

[16] *Id.* at 220.

the need for increased regulation to protect both the producer and the consumer:

> "The producer is often hundreds of miles in one direction, while the consumer may be as many hundred in another, from the *mart* at which the productions were sold and purchased. * * *
>
> A great trade has imperceptively grown upon us (particularly in New York), which I have sometimes thought, would have been more profitable to both producer and consumer, if proper laws, and practical, honest heads, had been placed over these vast interests, which so much affect the general health and comfort, as well as the *pockets* of our over-taxed citizens. . ."[17]

Following Shattuck's report and this expansion in trade, boards of health were established in cities, counties and states throughout the country.[18] Congress itself initially enacted broad food and drug legislation for the District of Columbia in 1888[19] and substantially strengthened it in 1898.[20]

B. Enactment of Federal Laws in the 1900s

Although statutes were enacted by Congress to regulate foreign commerce in food and drugs during the 1800s,[21] no

[17]T.F. De Voe, *The Market Assistant* 9 (1867).

[18]There is no compilation of all of these laws and regulations. Some of the state laws were collected and described or reproduced in A.J. Wedderburn, *Special Report on the Extent and Character of Food Adulterations*, USDA Bull. No. 32 (1892) and W.D. Bigelow, *Foods and Food Control*, USDA Bull. No. 69, pts. I-IV (1902). State regulations, and county and local laws and regulations, were not included. *See also* USDA, *Officials Charged with the Enforcement of Food Laws in the United States and Canada*, Bu. of Chem. Circ. No. 16 (1904) and Bu. of Chem. Circ. No. 16 (rev.)(1905).

[19]25 Stat. 549 (1888).

[20]30 Stat. 246 (1898).

[21]*E.g.*, 9 Stat. 237 (1848)(imported drugs); 22 Stat. 451 (1883) and 29 Stat. 604 (1897)(imported tea); 26 Stat. 414 (1890), 26 Stat. 1089 (1891), 30 Stat. 151, 210 (1897), and 30 Stat. 947, 951 (1899)(imported and exported food).

federal law was enacted during the 19th century to deal broadly with the safety and effectiveness of food and drugs marketed throughout the United States.[22]

In January 1879, Dr. E.R. Squibb delivered a major address to the Medical Society of the State of New York, proposing enactment of a nationwide food and drug law.[23] He began his remarks with a strong statement on the need for uniform national regulation of these articles:

> "It is self-evident that a law to be most effective in preventing the adulteration of food and medicine should be general or national in order to secure universality and uniformity of action . . ."[24]

Only ten days later, the first comprehensive federal legislation was introduced in Congress.[25] Because of strong feelings in Congress that this was properly a matter for state and local regulation[26], federal legislation was debated in Congress from 1879 to 1906. Throughout this time, the need for national uniformity in regulation of food and drugs was an important argument in favor of the legislation.[27] The Director of the

[22]A statute to regulate smallpox vaccine enacted in 2 Stat. 806 (1813) was repealed in 3 Stat. 677 (1822) after an error in its administration, on the ground that the subject matter should be left to regulation by the states.

[23]E.R. Squibb, *Proposed Legislation on the Adulteration of Food and Medicine* (1879).

[24]*Id.* at 3.

[25]H.R. 5916, 45th Cong., 3d Sess. (1879).

[26]As a result of congressional concern about the constitutionality of laws to control oleomargarine, 15 Cong. Rec. 2427(March 31, 1884), H.R. Rep. No. 1880, 49th Cong., 1st Sess. (1886),that legislation was enacted under the guise of a complex system of taxation, 24 Stat. 209 (1886).

[27]For example, the Chief of the USDA Food Laboratory argued for national legislation because "By no other means can we hope to secure laws uniform in their scope, requirements and penalties among ourselves . . ." W.D. Bigelow, *The Development of Pure Food Legislation*, 7 Science 505, 512 (April 15, 1898). The Chief of the USDA Bureau of Chemistry stated that legislation was necessary "to secure uniformity in the composition of drugs . . ." H.W. Wiley, *Drugs and Their Adulterations and The Laws Relating Thereto*, 2 Washington Medical Annals 205 (1903).

Bureau of Chemistry of the New York State Department of Health noted the need for uniform national regulation of food and drugs in 1903:

> ". . . it is very certain that the widely differing statutes relating to our food supply in the different States have worked much mischief, been the cause of much confusion, and seriously embarassed some useful industries. I think all who have studied the matter will be inclined to admit that uniformity in our food laws is much to be desired . . ."[28]

As has often happened in the history of food and drug regulation, a tragedy intervened to spur the enactment of national legislation. The Biologics Act of 1902[29] was enacted as a result of the distribution in St. Louis of tetanus-infected diphtheria antitoxin that resulted in the death of several children.[30] The law required that biological drugs sold in interstate commerce must be licensed and must be produced in licensed establishments.

Four years later, Congress enacted the Food and Drugs Act of 1906[31], which prohibited the adulteration or misbranding of any food or drug. Consistent with the concern expressed throughout the development of the legislation, the House Report stated that:

> ". . . the laws and regulations of the different States are diverse, confusing, and often contradictory. What one State now requires the adjoining State may forbid. Our food products are not raised principally in the States of their consumption.

---

[28]W.G. Tucker, *Food Adulteration: Its Nature and Extent, and How to Deal with It* 21 (1903).

[29]32 Stat. 728 (1902).

[30]R.A. Kondratas, *Death Helped Write the Biologics Law*, 16 FDA Consumer 23 (1982).

[31]34 Stat. 768 (1906).

> State boundary lines are unknown in our commerce, except by reason of local regulation and laws, such as State pure-food laws. It is desirable, as far as possible, that the commerce between the states be unhindered. One of the hoped-for good results of a national law on the subject of pure foods is the bringing about of a uniformity of laws and regulations on the part of the States within their own several borders."[32]

The 1906 Act, however, did not establish the basis for a comprehensive national regulatory scheme. It applied only to unbroken packages in interstate commerce, and only to the actual label of the product. Although premarket approval was required for biological drugs under the 1902 Act, no such authority was granted for other drugs under the 1906 Act. Nor was power granted to require informative labeling for either food or drugs. Thus, there were major regulatory gaps in the 1906 Act, with the result that these matters were left to the states.

These gaps were recognized in the decisions rendered by this Court under the 1906 Act, upholding state regulations which imposed requirements different from or in addition to those imposed by the federal government. The Court upheld a number of state requirements that applied only to food held for retail sale, and not contained in original unbroken packages after it had been shipped in interstate commerce.[33] These decisions were based on the jurisdictional provisions of the 1906 Act, which reached only goods that remained "unloaded, unsold, or in original unbroken packages" after interstate shipment[34], and on the restrictive construction of the Commerce

---

[32]H.R. Rep. No. 2118, 59th Cong., 1st Sess. 5-6 (1906).

[33]*Hebe Co.* v. *Shaw*, 248 U.S. 297 (1919); *Weigle* v. *Curtice Bros. Co.*, 248 U.S. 285 (1919); *Armour & Co.* v. *North Dakota*, 240 U.S. 510 (1916); *Price* v. *Illinois*, 238 U.S. 446 (1915).

[34]34 Stat. 768, 771, § 10 (1906).

Clause power from which those provisions were derived.[35] That narrow jurisdictional limitation was later eliminated in the 1938 Act.

Two of this Court's decisions under the 1906 Act were also based on the limited scope and coverage of the substantive provisions of that Act.[36] In both cases, the state requirements related to mandatory labeling, a matter not covered by the 1906 Act. Because the Court concluded that the federal regulatory scheme did not "cover the entire ground"[37] and that Congress had "limited the scope of its prohibitions,"[38] the state requirements were upheld.

In only one case arising under the 1906 Act did this Court confront a state regulation that affected an aspect of food labeling that was affirmatively regulated by that Act.[39] Both federal and state law required the food in question (a blend of corn and cane syrup) to bear an identity statement. The federal law did not specify the words to be used in such a statement. The state, however, imposed a specific form of words to be used and prohibited all others.[40] The Court's decision cannot be explained as an example of irreconcilable conflict between state and federal law, since the labeling requirement imposed by state law was also permitted under the federal statute. This Court stated that:

---

[35]*See Brown* v. *Maryland*, 12 Wheat. (25 U.S.) 419 (1827) and *United States* v. *Great Atlantic & Pacific Tea Co.*, 92 F.2d 610 (1937).

[36]*Corn Products Refining Co.* v. *Eddy*, 249 U.S. 427 (1919); *Savage* v. *Jones*, 225 U.S. 501 (1912).

[37]249 U.S. at 434, 225 U.S. at 532.

[38]225 U.S. at 532.

[39]*McDermott* v. *Wisconsin*, 228 U.S. 115 (1913).

[40]Section 8 of the Food and Drugs Act of 1906 provided that "mixtures" or "compounds" would not be deemed misbranded if sold under "distinctive names." 34 Stat. 768, 770, § 8 (1906). The state statute applied to "mixtures" of certain syrups, but prescribed specific names under which they were to be sold. 228 U.S. at 125-126.

> "Conceding to the state the authority to make regulations consistent with the Federal law for the further protection of its citizens against impure and misbranded food and drugs, we think to permit such regulation as is embodied in the statute is to permit a State to discredit and burden legitimate Federal regulations of interstate commerce, to destroy rights arising out of the Federal statute which have accrued both to the Government and the shipper, and to impair the effect of a Federal law which has been enacted under the Constitutional power of Congress over the subject."[41]

Thus, the state regulation was invalidated.

The limitations relating to both jurisdiction and substantive authority under the 1906 Act were removed by Congress in the Federal Food, Drug, and Cosmetic Act of 1938.[42] Under that statute, FDA is empowered to regulate all labeling, to impose any requirements for product information, to regulate every aspect of interstate commerce, to exercise premarket approval over new drugs and food additives, and to cover every other matter relating to the safety and effectiveness of food and drugs. When Congress considered enactment of this law, it stated that, recognizing the "problem of uniformity," the "States have unanimously urged the Federal Government to take leadership in modernizing existing law."[43] The technical adviser to the principal Senate sponsor and floor manager of the legislation reported a year after the 1938 act became law that all states had comprehensive food and drug laws at that time.[44] He recommended state legislation uniform with the new federal legislation:

---

[41]228 U.S. at 133-134.

[42]52 Stat. 1040 (1938), 21 U.S.C. § 301 *et seq.*

[43]S. Rep. No. 361, 74th Cong., 1st Sess. 3 (1935).

[44]O. Salthe, *State Food, Drug and Cosmetic Legislation and its Administration*, 6 L. & Contemp. Prob. 165, 167 (1939).

> "When the state legislatures delegate power to state officials to promulgate regulations there should be some definite provisions for uniformity of action with the federal laws, so as to eliminate the confusion that would result in trying to comply with conflicting control."[45]

Congress has also amended the law since 1938 to provide still further authority for FDA. In 1948, Congress expanded the jurisdiction of the 1938 Act to include any action with respect to a food or drug that results in the article becoming adulterated or misbranded after shipment in interstate commerce.[46] The Drug Amendments of 1962[47] increased FDA authority over all drugs and the Drug Listing Act of 1972[48] provided FDA with authority to determine vital information about all drug products marketed in this country.

In 1944, Congress recodified the entire Public Health Service Act.[49] Two provisions in that law provide FDA with regulatory authority over drugs. Section 351 of the Public Health Service Act[50] recodified the provisions of the Biologics Act of 1902. As noted above, these provisions require premarket approval of biological drugs and include full power over the production and labeling of these products. In 1970, as a result of conflicts between court decisions[51], Congress amended section 351 to make it clear that it covered blood, blood components, and blood derivatives.[52]

---

[45] *Id.* at 174-175.

[46] 62 Stat. 582 (1948), amending 21 U.S.C. § 331(k). *See* W.W. Goodrich, *The Applicability of the Federal Food, Drug, and Cosmetic Act to Intrastate Commerce*, 3 Food Drug Cosm. L.J. 332 (1948).

[47] 76 Stat. 780 (1962).

[48] 86 Stat. 559 (1972).

[49] 58 Stat. 682 (1944).

[50] *Id.* at 702, 42 U.S.C. § 262.

[51] *Compare United States* v. *Steinschreiber*, 219 F. Supp. 373 (S.D.N.Y. 1963), *aff'd per curiam*, 326 F.2d 759 (2d Cir.), *cert. denied*, 376 U.S. 962 (1964), *with Blank* v. *United States*, 400 F.2d 302 (5th Cir. 1968).

[52] 84 Stat. 1297, 1308 (1970). *See* H.R. Rep. No. 91-1035, 91st Cong., 2d Sess. 1-2 (1970).

The second important provision in the Public Health Service Act is section 361[53], which broadly authorizes any action necessary "to prevent the introduction, transmission, or spread of communicable diseases" in intrastate or interstate commerce. This provision allows FDA to undertake whatever form of regulation of food or drugs may be necessary to protect the public from any source of communicable disease.[54]

II. Comprehensive Modern Statutes and Regulations Assure Every Citizen that Food and Drugs Are Safe and Effective Throughout Every Jurisdiction in this Country.

The federal statutes enacted, amended, and strengthened throughout the 1900s now provide FDA with comprehensive authority to regulate every aspect of the food and drug supply. The nature of the subject matter, the consistent declaration of congressional purpose in enacting these statutes, the pervasive coverage of intrastate and interstate commerce, the comprehensive authority over every aspect of food and drugs, the dominant federal interest in a nationwide regulatory system for food and drugs, and the detailed implementing regulations promulgated by FDA, evince a congressional intent to occupy this field. Additional or different state and local laws and regulations obstruct and frustrate this congressional purpose and thus can no longer be justified.

A. The Collection, Processing, Marketing,and Use of Blood and Blood Products in this Country Are Thoroughly Regulated by FDA Pursuant to These Federal Statutes

Prior to 1972, the Biologics Act of 1902 and the later-enacted sections 351 and 361 of the Public Health Service Act were administered by the United States Public Health Service. In

---

[53] 58 Stat. 682, 703 (1944), 42 U.S.C. § 264(a).

[54] *E.g.*, *Louisiana* v. *Mathews*, 427 F. Supp. 174 (E.D. La. 1977); *United States* v. *Shinnick*, 219 F. Supp. 789 (E.D.N.Y. 1963).

1972, however, the administration of these statutes was transferred to FDA.[55] In 1962, moreover, the status of blood as a "drug" under the Federal Food, Drug, and Cosmetic Act was upheld in the courts.[56] Thus, the consolidation in 1972 of all statutory authority for the regulation of blood and blood products in FDA set the stage for development of a single comprehensive federal regulatory approach.

At the same time that this regulatory authority was consolidated in FDA, the Department of Health, Education, and Welfare (HEW), within which FDA was located, undertook to establish a National Blood Policy. That National Blood Policy, adopted in 1973[57], brought together all interested private and public organizations to consider both regulatory and nonregulatory aspects of providing an adequate supply of vital blood products for the needs of the country. The National Blood Policy was designed:

> "(4) To encourage, foster, and support measures to enhance resource-sharing and area-wide cooperation in the collection, processing, distribution, and utilization of blood, in order to make the most effective use of the national supply."[58]

As part of the National Blood Policy, HEW determined that it was "the policy of the United States Government:"

> "(7) To employ the full regulatory authorities now vested in the Federal Government and to seek such additional authority as may be necessary and appropriate for the purpose of assuring uniform adherence to the highest

[55]37 Fed. Reg. 12865 (June 29, 1972), 21 C.F.R. § 5.10(a)(iv) & (v).

[56]*United States* v. *Calise*, 217 F. Supp. 705 (S.D.N.Y. 1962).

[57]39 Fed. Reg. 9326 (March 8, 1974); 39 Fed. Reg. 32702 (September 10, 1974).

[58]39 Fed. Reg. 9327, 9328 (March 8, 1974).

> attainable standards of practice in blood banking, including plasmapheresis and plasma fractionation."[59]

No additional authority was identified at that time, or in the ten years since then, that would be needed to achieve those "highest attainable standards." The implementation plan for the National Blood Policy stated that "the coordination of inventories across the nation that is called for in the following plan will make better use of periodic surpluses and will help to even out blood supplies to minimize the effects of localized shortages and to reduce the absolute numbers of donors who must be recruited during a given period."[60] It was intended to "organize blood banks and the transfusion facilities they serve within a national system"[61] organized and coordinated by the American Blood Commission.

Under its consolidated statutory authority, and in conformity with the National Blood Policy, FDA began in 1972 to apply new regulatory requirements to blood and blood products (shortened to "blood" in the following discussion).[62] FDA required registration of blood establishments[63], promulgated regulations governing current good manufacturing practices (GMP) in the collection, processing, and storage of blood[64], determined that advertising for blood is subject to section

[59]39 Fed. Reg. 9326, 9329 (March 8, 1974); 39 Fed. Reg. 32702 (September 10, 1974).

[60]39 Fed. Reg. at 9328.

[61]*Id.*

[62]*See generally*, H.M. Meyer, *Does Government Regulation Work?*, in D.B. Johnson, ed., *Blood Policy Issues and Alternatives* 91, 93-99 (1976).

[63]37 Fed. Reg. 17419 (August 26, 1972); 38 Fed. Reg. 2965 (January 31, 1973); 40 Fed. Reg. 52788 (November 12, 1975). *See also* 45 Fed. Reg. 19316 (March 25, 1980); 45 Fed. Reg. 64601 (September 30, 1980); 49 Fed. Reg. 34448 (August 31, 1984).

[64]39 Fed. Reg. 18614 (May 28, 1974); 40 Fed. Reg. 53532 (November 18, 1975). Additional recordkeeping requirements were proposed, 41 Fed. Reg. 18095 (April 30, 1976), but withdrawn as unnecessary, 43 Fed. Reg. 59098 (December 19, 1978).

502(n) of the 1938 Act and the implementing regulations[65], established responsibility for regulation of containers for collection or processing of blood[66], promulgated donor classification labeling requirements[67], began to regulate specific product labeling[68], announced proposed requirements for records and reports of adverse reactions and product experiences[69], proposed to require reports on errors and accidents in plasmapheresis[70], conducted a donor safety workshop for leukapheresis[71], established guidelines for various procedures[72], revised the calibration requirements for certain blood equipment[73], proposed revised labeling requirements for blood[74], revised hepatitis testing restrictions[75], conducted a review of all the federal blood regulations[76], subjected therapeutic plasma exchange to FDA regulation[77], and took a wide variety of

[65]39 Fed. Reg. 43654 (December 17, 1974).

[66]40 Fed. Reg. 33971 (August 13, 1975).

[67]40 Fed. Reg. 53040 (November 14, 1975); 41 Fed. Reg. 4955 (February 3, 1976); 41 Fed. Reg. 8523 (February 27, 1976); 42 Fed. Reg. 11018 (February 25, 1977); 43 Fed. Reg. 2142 (January 13, 1978).

[68]43 Fed. Reg. 15779 (April 14, 1978).

[69]44 Fed. Reg. 24233 (April 24, 1979).

[70]45 Fed. Reg. 52821 (August 8, 1980).

[71]45 Fed. Reg. 58969 (September 5, 1980).

[72]45 Fed. Reg. 63144 (September 23, 1980); 42 Fed. Reg. 25381 (May 17, 1977); 46 Fed. Reg. 24694 (May 1, 1981); 46 Fed. Reg. 52430 (October 27, 1981); 46 Fed. Reg. 48768 (October 2, 1981); 46 Fed. Reg. 49204 (October 6, 1981); 49 Fed. Reg. 13079 (April 2, 1984).

[73]44 Fed. Reg. 34515 (June 15, 1979); 45 Fed. Reg. 9261 (February 12, 1980).

[74]45 Fed. Reg. 72416 (October 31, 1980); 46 Fed. Reg. 47623 (September 29, 1981).

[75]44 Fed. Reg. 76811 (December 28, 1979); 46 Fed. Reg. 35121 (July 7, 1981); 46 Fed. Reg. 36134 (July 14, 1981); 48 Fed. Reg. 46815 (October 14, 1983); 49 Fed. Reg. 26717 (June 29, 1984).

[76]47 Fed. Reg. 12358 (March 23, 1982).

[77]48 Fed. Reg. 14048 (April 1, 1983).

other actions. In addition, FDA continued to establish safety standards for all of the blood products allowed by FDA to be marketed pursuant to federal licenses: platelet concentrate (human)[78], normal serum albumin (human) and plasma protein fraction (human)[79], plasma collected and manufactured by plasmapheresis[80], blood grouping serum[81], single donor plasma (human)[82], reagent red blood cells[83], whole blood (human)[84], blood group substances[85], and antihemophilic factor (human)[86].

[78]36 Fed. Reg. 6835 (April 9, 1971); 39 Fed. Reg. 2008 (January 16, 1974); 40 Fed. Reg. 4300 (January 29, 1975); 42 Fed. Reg. 10982 (February 25, 1977); 45 Fed. Reg. 2852 (January 15, 1980); 45 Fed. Reg. 27926 (April 25, 1980); 45 Fed. Reg. 45924 (July 8, 1980); 47 Fed. Reg. 49017 (October 29, 1982).

[79]37 Fed. Reg. 12505 (June 24, 1972); 40 Fed. Reg. 7456 (February 20, 1975); 42 Fed. Reg. 27575 (May 31, 1977); 42 Fed. Reg. 44228 (September 2, 1977); 48 Fed. Reg. 19897 (May 3, 1983); 48 Fed. Reg. 34480 (July 29, 1983); 49 Fed. Reg. 1685 (January 13, 1984); 49 Fed. Reg. 2243 (January 19, 1984).

[80]37 Fed. Reg. 17419 (August 26, 1972); 38 Fed. Reg. 19362 (July 20, 1973); 39 Fed. Reg. 26161 (July 17, 1974); 39 Fed. Reg. 35187 (September 30, 1974); 40 Fed. Reg. 41799 (September 9, 1975); 41 Fed. Reg. 10762 (March 12, 1976); 42 Fed. Reg. 18129 (April 5, 1977); 42 Fed. Reg. 21772 (April 29, 1977); 42 Fed. Reg. 25381 (May 17, 1977); 42 Fed. Reg. 25339 (May 17, 1977); 42 Fed. Reg. 37545 (July 22, 1977); 43 Fed. Reg. 9804 (March 10, 1978); 43 Fed. Reg. 19461 (May 5, 1978); 44 Fed. Reg. 60332 (October 19, 1979); 45 Fed. Reg. 28358 (April 29, 1980); 45 Fed. Reg. 45924 (July 8, 1980); 45 Fed. Reg. 79092 (November 28, 1980); 45 Fed. Reg. 80500 (December 5, 1980); 46 Fed. Reg. 57480 (November 24, 1981); 47 Fed. Reg. 12358 (March 23, 1982); 47 Fed. Reg. 15329 (April 9, 1982); 47 Fed. Reg. 30968 (July 16, 1982).

[81]38 Fed. Reg. 31312 (November 13, 1973); 40 Fed. Reg. 52623 (November 11, 1975); 42 Fed. Reg. 54534 (October 7, 1977); 42 Fed. Reg. 61257 (December 2, 1977); 43 Fed. Reg. 19844 (May 9, 1978); 46 Fed. Reg. 35122 (July 7, 1981); 47 Fed. Reg. 22519 (May 25, 1982).

[82]40 Fed. Reg. 52619 (November 11, 1975); 42 Fed. Reg. 59873 (November 22, 1977).

[83]40 Fed. Reg. 52621 (November 11, 1975); 43 Fed. Reg. 10554 (March 14, 1978).

[84]43 Fed. Reg. 2890 (January 20, 1978); 43 Fed. Reg. 34457 (August 4, 1978); 45 Fed. Reg. 72422 (October 31, 1980); 48 Fed. Reg. 33494 (July 22, 1983).

[85]43 Fed. Reg. 11716 (March 21, 1978); 44 Fed. Reg. 20673 (April 6, 1979).

[86]45 Fed. Reg. 22975 (April 4, 1980).

FDA has, in short, considered every aspect of the regulation of blood and blood products. Without doubt, it has decided to issue regulatory requirements in some areas where state, county, and local governments might conclude not to regulate, and it has decided to refrain from issuing regulatory requirements in other areas where state, county, or local governments might conclude that regulation should be undertaken. If every state, county, or local government in the country were to decide — like Hillsborough County — to issue its own different or additional requirements on top of those imposed by FDA, there would be chaos. FDA's comprehensive and detailed regulatory scheme for blood exhibits an extraordinarily deep evaluation of all aspects of blood regulation, and permits no supplementary requirements by state, county, or local governments. Such additional or different requirements would clearly frustrate the federal purpose of a comprehensive National Blood Policy and uniform national regulatory requirements to implement it.

B. The Production, Processing, Marketing, and Use of All Food and Drugs in this Country Are Regulated by FDA in an Equally Comprehensive Way

This case illustrates only one aspect of FDA regulation, for blood and blood products. Other drugs and food are also subject to detailed and comprehensive regulatory control by FDA.

III. Repeated Attempts To Achieve National Uniformity in the Regulation of Food and Drugs by Informal Persuasion Have Failed.

Following enactment of the Food and Drugs Act of 1906, FDA's predecessor agency, the USDA Bureau of Chemistry, made major efforts to implement the congressional intent[87] of national uniformity in the regulation of food and drugs. The 1914 Annual Report of the Bureau of Chemistry[88] reported

[87]Note 32 *supra*.

[88]The annual reports of the Bureau of Chemistry and FDA are reprinted in Food Law Institute, *Federal Food, Drug, and Cosmetic Law Administrative Reports, 1907-1949* (1951).

cooperative efforts with state officials "for the purpose of fixing working standards for foods and drugs" that "should serve as a uniform guide in the enforcement of the food and drug laws throughout the country" and thus "should very largely overcome the lack of uniformity."[89] A report on the progress achieved by the Bureau of Chemistry during the first ten years under the 1906 Act, contained in the 1917 Annual Report, related attempts to deal with "much confusion and apparent conflict between the local and Federal laws and the local and Federal administration of the laws," resulting in "extra cost, which naturally was passed on to the ultimate consumer."[90] The 1921 Annual Report similarly reflected the fact that "both officials and manufacturers complained greatly of the lack of uniformity in the exercise of food control by the Federal and State Governments:"[91]

> "Lack of uniformity increases the cost of doing business, and the increased cost is usually passed on to the consumer. It arises not merely from differences in the various laws but also from differences in the interpretation of the laws by the officials and the application by them of different standards to the same product in different jurisdictions."

In 1924, an attempt was made to devise "a uniform method of procedure" for regulation of both federal and state food and drug laws.[92] FDA has continued to deal with this persistent problem of nonuniform food and drug laws in the years since.[93]

State and local officials have also been concerned about this problem. The original constitution of the Association of Official

[89]1914 Annual Report at 1, *id.* at 321.

[90]1917 Annual Report at 12-13, *id.* at 366-367.

[91]1921 Annual Report at 7, *id.* at 459.

[92]1924 Annual Report at 26, *id.* at 592.

[93]*E.g.*, J.C. Pearson, *Uniform State Food Laws*, 14 Food Drug Cosm. L.J. 183 (1959); J.P. Hile, *Remarks on Eliminating Duplication and Promoting Uniformity*, 44 AFDO Quart. Bull. 37 (1980).

Agricultural Chemists (now the Association of Official Analytical Chemists), adopted in 1884, stated that the objectives were "to secure, as far as possible, uniformity in legislation . . . and uniformity and accuracy in the methods and results" of analysis.[94] AOAC has consistently sought this objective for 100 years.

In 1897, representatives from ten states met "for the purpose of forming a national Association . . . with the end in view of producing, as nearly as conditions and laws would permit, uniformity of action in the enforcement of such [food and drug] laws."[95] The constitution of the resulting organization, adopted in 1897, stated that the purpose was:

> ". . . to promote and foster such legislation as would tend to protect public health and prevent deception . . . — also to promote uniformity in legislation and rulings . . . ."[96]

That organization, now the Association of Food and Drug Officials (AFDO), includes as members the regulatory officials from federal, state, county, and local governments. AFDO has urged the principle of national uniformity from its first organization. In 1941, for example, the AFDO President wrote an editorial criticizing "trade barriers that force many producers and manufacturers to live under the virtual dictatorship of localized bureaucracy," and urging state food and drug officials to "Discourage the enactment of laws that make it impossible for legitimate industry of one state to engage in trade in another under conditions which are fair and equitable" and to "Encourage the enactment of uniform laws and the adoption of uniform regulations looking toward honest protection of the consumer."[97] That year, AFDO adopted a resolution to express "active and continuing interest in the enactment of uniform

---

[94]K. Helrich, *The Great Collaboration: The First One Hundred Years of the Association of Official Analytical Chemists* 9 (1984).

[95]W.F. Reindollar, *The Association of Food and Drug Officials*, 6 Food Drug Cosm. L.J. 52, 53 (1951).

[96]*Id.* at 54.

[97]5 AFDOUS Quart. Bull. 2 (1941).

legislation" and "emphatically express its disapproval of the tendency toward the enactment of legislation which constitutes definite barriers to Commerce between the states."[98] Since 1940, the Association has repeatedly adopted resolutions urging enactment of uniform food and drug legislation.[99] Nonetheless, in 1973 the Association found it necessary to pass yet another resolution acknowledging, as well as disapproving, "a growing trend . . . that some States and local agencies are passing laws, regulations, or ordinances which are inconsistent with the principle of uniformity to which A.F.D.O.U.S. is committed."[100] More recently, yet another AFDO committee has made recommendations for achieving national uniformity in food and drug regulation.[101]

AFDO has sponsored the development of uniform state legislation under both the 1906 Act and the 1938 Act, and has periodically revised this legislation to reflect changes in the federal law.[102] Since 1938, state officials have admonished their colleagues to achieve adoption of this legislation, and to administer state and local laws in a manner consistent with federal interpretations,[103] but to no avail.

---

[98]5 AFDOUS Quart. Bull. 8 (1941).

[99]*E.g.*, 4 AFDOUS Quart. Bull. 3-4 (1940); 31 AFDOUS Quart. Bull. (Proceedings Issue) 73 (1967); 33 AFDOUS Quart. Bull. (Proceedings Issue) 46-47 (1969).

[100]37 AFDOUS Quart. Bull. (Proceedings Issue) 19 (1973).

[101]"AFDO Takes First Step To Selective Preemption," Food Chemical News, June 25, 1984, at 49-53.

[102]Note 44 *supra;* O.J. Wiemann, *Report on the Revision of the Uniform State Food, Drug and Cosmetic Bill*, 17 Food Drug Cosm. L.J. 218 (1962). The current version of the Uniform State Food, Drug and Cosmetic Bill may be found in Food Drug Cosm. L. Rep. (CCH) ¶ 10,102. Earlier versions under the 1938 Act may be found in "Consumer Protection Activities of State Governments," H.R. Rep. No. 445, 88th Cong., 1st Sess. 88, 104 (1963).

[103]For examples of statements of state and local food and drug officials endorsing national uniformity, see T.E. Sullivan, *The Effect of Uniform Legislation on State Control*, 3 Food Drug Cosm. L.J. 444 (1948); J. Trichter,

Dozens of reports and articles reflect the repeated failure of these attempts to achieve uniformity through informal persuasion. A USDA report in 1939 found that varying or inconsistent state requirements created increasingly serious barriers to national food distribution.[104] Two studies conducted by the House Committee on Government Operations in 1963 revealed widely differing approaches to regulation of food and drugs among the state governments.[105] A two-year study on state and local food and drug programs, conducted by the Public Administration Service for FDA, concluded in 1965 that:

> "The general food and drug laws of the states fail to reveal a basic uniformity among themselves or inadequate correspondence with federal legislation. * * * Differences in laws and regulations are excessive, and many serve no useful purpose; the total body of state and local food and drug laws is a confusing and disjointed mass."[106]

The National Commission on Food Marketing, established by Congress to appraise the marketing structure of the industry[107], stated in 1966 that "conflicts among the profusion of

---

The Federal Food, Drug and Cosmetic Act and the New York Sanitary Code, 11 Food Drug Cosm. L.J. 86 (1956); T.E. Sullivan, *Uniform State Laws and the Impact of Federal Amendments*, 14 Food Drug Cosm. L.J. 167 (1959); E.L. Randall, *Factors Affecting the States' Adoption of the Food-Additives Law as Well as Other Recent Amendments to the Federal Food, Drug, and Cosmetic Act*, 14 Food Drug Cosm. L.J. 172 (1959); J.F. Lakey, *Uniform State Food Laws and Amendments*, 14 Food Drug Cosm. L.J. 179 (1959); T.E. Sullivan, *The Desirability of Uniformity Between State and Federal Laws on Food Additives*, 16 Food Drug Cosm. L.J. 34 (1961); F.E. Fisher, *Federal/State Concurrent Regulations*, 29 Food Drug Cosm. L.J. 20 (1974).

[104] USDA, *Barriers to Internal Trade in Farm Products* (1939).

[105] "Consumer Protection Activities of State Governments," H.R. Rep. No. 445, 88th Cong., 1st Sess. (1963), and H.R. Rep. No. 921, 88th Cong., 1st Sess. (1963).

[106] Public Administration Service, *A Study of State and Local Food and Drug Programs* 8 (1965).

[107] 78 Stat. 269 (1964).

State regulations . . . are a significant burden on interstate trade in food products" and concluded that:

> "We therefore believe that a concerted effort should be made to effect uniformity among State regulations that obstruct trade in foods across State lines."[108]

The Report of the White House Conference on Food, Nutrition and Health in 1969 similarly found that "Under present Federal, State and local law, different and often inconsistent regulatory requirements . . . prevail throughout the Nation," and that these requirements:

> ". . . result in artificial trade barriers that impede the orderly marketing of foods, hinder sound nutrition, raise the cost of new foods to consumers, and directly interfere with the public interest. * * * This situation cannot be justified on public health grounds, and reflects the lack of any attempt to establish and maintain a national policy on foods that reflects the interest of consumers."[109]

The Report of the White House Conference therefore recommended "Uniform application of all regulatory requirements throughout the Nation, enforceable by Federal, State, and local officials."[110] A 1980 study by the Joint Economic Committee of Congress also reflected the fact that "in the area of drug labeling, State and Federal statutes can differ."[111] The problem of non-uniform laws, regulations, and interpretations has pro-

---

[108] *Food From Farmer to Consumer: Report of the National Commission on Food Marketing* 112 (1966).

[109] *Report of the White House Conference on Food, Nutrition and Health* 124-125 (1969).

[110] *Id.* at 117.

[111] "An Inquiry into Conflicting and Duplicative Regulatory Requirements Affecting Selected Industries and Sectors," 96th Cong., 2d Sess. 24 (1980) (Joint Committee Print).

duced more articles in the Food Drug Cosmetic Law Journal, since its first issue in 1946, than any other subject.[112]

Thus, in defiance of the congressional intent to achieve a consistent and unified national regulatory program, it is apparent that none of the extensive attempts at persuasion during the past 100 years has brought the country nearer to national uniformity in the regulation of food and drugs. Such approaches have repeatedly failed and will continue to fail in the future.

IV. State and Local Laws and Regulations That Are Different From or in Addition To Federal Laws and Regulations Constitute Trade Barriers That Frustrate the Purpose of Comprehensive Federal Regulation in this Field.

The United States has become one large nationwide market for food and drugs. Although blood and blood products are comparatively recent articles of national commerce, compared to other drugs and to food, the market for blood and blood products has now become national and even international in scope.[113] It was this realization, indeed, that led to the development of the National Blood Policy in 1973.[114] The need for blood and blood products, like the need for other drugs and for food, knows no political boundaries. The National Blood Policy was formulated in 1973 precisely to allow the sharing of blood supplies within regions of the country or, in times of short

---

[112] *E.g.*, notes 93 & 103 *supra;* R.P. Schipa, *The Desirability of Uniform Food Law*, 3 Food Drug Cosm. L.J. 518 (1948); H.A. Prentice, *Uniform Food Laws*, 4 Food Drug Cosm. L.J. 502 (1949); C.R. Miller, *Uniform Food Laws*, 6 Food Drug Cosm. L.J. 924 (1951); G.M. Burditt, *The Importance of Uniformity Among State Food and Drug Laws*, 26 Food Drug Cosm. L.J. 96 (1971); M.S. Thompson, *What Price Uniformity?*, 30 Food Drug Cosm. L.J. 567 (1975); R.L. Frank, *Food Labelling — The Case for National Uniformity*, 34 Food Drug Cosm. L.J. 512 (1979).

[113] Notes 58 & 60 *supra;* Office of Technology Assessment, *Blood Policy & Technology*, Rep. No. OTA-H-260, ch. 1 (1985).

[114] Note 57 *supra*.

supply, between regions.[115] Federal regulatory efforts were designed to achieve uniformity in regulation to facilitate that policy. Allowing state, county, and local governments to superimpose on the federal regulatory system additional or different requirements would frustrate the National Blood Policy and prevent the efficient distribution and use of these life saving products.

Nonuniform laws, regulations, interpretations and other requirements have a direct and immediate adverse impact upon the national interest. They result in an enormous economic burden upon consumers, with no corresponding public health benefits. A single uniform regulatory system, consistent with the pervasive regulatory program enacted by Congress and implemented by FDA, is more efficient and more effective than balkanized regulation through differing or additional requirements that vary from judisdiction to jurisdiction throughout the country.

Citizens who live in one part of the country are no less entitled to protection than those who live in another. Our citizens also travel widely throughout the country, and are entitled to the same protection in every state, county, and city they visit. Determinations about the safety of food and drugs must therefore be consistent in every jurisdiction in this country.

Recognition that Congress and FDA have established uniform requirements for the safety and effectiveness of food and drugs throughout the country will enhance consumer protection. Enforcement of such requirements will be accomplished more efficiently as state, county, and local officials join in a cooperative venture with federal officials to ensure nationwide compliance with clear and uniform regulatory requirements, thus substantially increasing the effectiveness of public expenditures.

---

[115] *Id.*

National uniformity in food and drug regulation does not mean that state and local officials must be subservient to the federal government or that they cannot contribute to the development and consideration of improvements in the regulatory approach adopted by FDA. Under existing FDA regulations, state and local officials may petition FDA to change any existing regulation or interpretation, or to impose new requirements, in order to improve national regulatory policy.[116] State and local officials may similarly comment on all FDA proposals and otherwise participate in FDA proceedings.[117] Thus, a fully coordinated and consistent national regulatory policy, with the active participation of state and local officials, has been provided for under existing law.

In an article published in 1983, the Counsel to the Vice President stated that President Reagan's "New Federalism" initiative, which is designed to encourage greater responsibility at the state and local level, includes:

> ". . . recognition that state and local administration of regulatory programs may conflict in some instances with other goals of regulatory relief or with other important federal interests. For example, individual states may operate specific programs more effectively than the federal government, but the combined effect of disparate state regulatory standards may intolerably burden interstate commerce, thus requiring uniform federal regulation."[118]

Recognizing "the need for a strong central government to promote commerce and other federal interests,"[119] he distinguished between those matters that are primarily local in nature and those that involve such "burdens on interstate commerce"[120] that national uniformity is required.

---

[116]21 C.F.R. § 10.30.

[117]21 C.F.R. § 10.40.

[118]C.B. Gray, *Regulation and Federalism*, 1 Yale J. Reg. 93 (1983).

[119]*Id.* at 95-96.

[120]*Id.* at 96.

As recently as December 1984, the Administrative Conference of the United States issued a report and recommendation that echoed these principles.[121] While recognizing that "state governments are normally in a better position than the federal government to determine the types of regulations that will serve the interests of the states' citizens," the report also found that "States sometimes have an incentive, however, to impose regulations that advance state interests at the expense of other states' interests or of national interests." The report concluded that, because of the limited "checks on state regulation that harms the national interest:"

> "states possess, in practice, the power to make regulatory choices that produce net benefits within the state but that produce substantial net detriments on a national level. Without an additional federal constraint on state regulatory power, states can be expected to regulate in this manner frequently."

The Administrative Conference therefore recommended that the problem of national uniformity in regulatory policies be directly pursued in order to protect nationwide interests.

State and local governments have clearly failed to recognize the comprehensive federal regulatory scheme for food and drugs that has been enacted into law by Congress and implemented by FDA during the past 50 years. This Court must therefore give effect to the congressional intent to establish one nationwide uniform regulatory system that will fully protect both the interests of consumers and the free flow of food and drugs in interstate commerce.

---

[121]49 Fed. Reg. 49838 (December 24, 1984).

CONCLUSION

For the reasons set forth above, the judgment of the Court of Appeals should be affirmed.

Respectfully submitted,

PETER BARTON HUTT
Counsel of Record
Covington & Burling
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20044
(202) 662-5522

STEPHEN A. BROWN
Grocery Manufacturers of
America, Inc.
Suite 800
1010 Wisconsin Avenue, N.W.
Washington, D.C. 20007
(202) 337-9400

Counsel for Amicus Curiae

March 29, 1985

No. 83-1925

IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

HILLSBOROUGH COUNTY, FLORIDA, *et al.*,
Appellants

v.

AUTOMATED MEDICAL LABORATORIES, INC.,
Appellees

On Appeal from the United States Court of Appeals for the Eleventh Circuit

---

APPELLANTS' REPLY BRIEF

JOE HORN MOUNT
Counsel of Record
Hillsborough County Attorney
P.O. Box 1110
Tampa, Florida 33601
(813) 272-5670

EMELINE C. ACTON
Assistant Hillsborough
County Attorney

WILSON - EPES PRINTING CO., INC. - 789-0096 - WASHINGTON, D.C. 20001

TABLE OF CONTENTS

TABLE OF AUTHORITIES

IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

No. 83-1925

HILLSBOROUGH COUNTY, FLORIDA, *et al.*,
Appellants

v.

AUTOMATED MEDICAL LABORATORIES, INC.,
Appellees

On Appeal from the United States Court of Appeals for the Eleventh Circuit

---

APPELLANTS' REPLY BRIEF

In their opening brief, appellants argued that the Court of Appeals erred in holding that the FDA's regulations, which impose certain minimum standards on plasmapheresis centers, *impliedly* preempted all attempts by Hillsborough County to impose any additional requirements on these centers to protect the public health and safety. Appellee and its *amici* confuse the law of express and implied preemption. If an *express* statement of pre-emptive intent exists, implied pre-emption is not involved; the statement must govern. *Jones v. Rath Packing Co.*,

430 U.S. 519 (1977). Appellee's and its amici's responses to our contentions warrant a brief reply.[1]

I. The FDA's Clear Statement That It Did Not Intend to Preempt Local Regulation Precludes Implied Preemption.

In 1973, the Commissioner of the FDA stated that the federal plasma regulations "are *not intended* to usurp the powers of state or local authorities to regulate plasmapheresis procedures in their localities." 38 Fed. Reg. 19365 (1973). Incredibly, appellee and ABRA argue that, even though the FDA expressed its intent *not to preempt*, this Court still should imply later preemption by the FDA based upon its subsequent regulations and general statements regarding uniformity.[2] Appellee's suggestion stands the preemption doctrine on its head. Local laws are presumed valid unless federal law clearly requires otherwise. See, *e.g.*, *Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981). Under the theory espoused by appellee and ABRA, whenever a federal agency enacted minimum standards for a particular industry, it would preclude all complementary state and local standards unless it declared expressly

[1] We will refer to the individual *amicus* briefs as follows: the American Blood Commission ("ABC Br."), the American Blood Resources Association ("ABRA Br."), and the Grocery Manufacturers of America ("GMA Br.").

[2] ABRA quotes part of a statement by the FDA as justification for implying preemption of state and local regulation: "The Commissioner finds these (State) programs are inadequate." (ABRA's brief, p. 12, n. 14). The correct quotation is that the Commissioner found state programs "inadequate to keep blood containing hepatitis virus *from the channels of interstate commerce.*" 39 Fed. Reg. 18614-5 (1974). Regulation of interstate commerce is unquestionably an area over which the federal government, as opposed to local government, has primary control. But, conversely, it is local governments' unique power to regulate health and safety procedures in their own localities which led to the FDA's opinion that its regulations do not preempt such powers. 38 Fed. Reg. 19365 (1973); United States' Brief at 18-19.

that it did *not* intend its regulation to be exclusive. Moreover, an agency's declared intention *not* to preempt state law would be effectively nullified each time it adopted new standards. There is no reason for this Court to disregard the FDA's clear statement of its intent not to preempt local regulation.[3]

II. The National Blood Policy Does Not Require Exclusive Federal Standards.

The goals of the FDA are to ensure, on the one hand, plasma quality and donor safety and, on the other hand, an adequate supply of quality blood. Appellee and ABRA do not claim that the County's regulations would frustrate the goals of donor safety or plasma quality. The basic argument of appellee (Br. 30-31), ABRA (Br. 14-18) and ABC (Br. 18-19) is that the blood supply is a matter of national concern as embodied in the National Blood Policy (39 Fed. Reg. 32702 (1974)).

But, as we pointed out in our opening brief, the National Blood Policy does not include plasmapheresis. As the Acting Assistant Secretary of Health stated: "Although this comprehensive policy accelerates the evolution of an all-voluntary supply of blood and blood components, *it leaves untouched* for the time being, the commercial acquisition of plasma and the preparation and marketing of plasma derivatives, and the commercial acquisition of blood for preparation of diagnostic reagents." 39 Fed. Reg. 32702 (1974) (Emphasis supplied). Although ABRA states (Br. 12 n.13) that commercial plasmapheresis is covered under all aspects of the Policy except its promotion of voluntary donors, the only im-

[3] ABRA argues (Br. 11) that the question of preemption is a legal one and must be decided by this Court, not the federal agency involved. But ABRA's argument disregards the fact that the first *legal* question to be answered by the Court is whether the FDA expressed its intent regarding preemption. As the FDA clearly and expressly did *not* intend to preempt, the legal issue ends there.

pact upon plasmapheresis which the Policy undertook was to "promote the acquisition of information upon which future policy could be developed." 39 Fed. Reg. 32702 (1974).

Based on their view of the National Blood Policy, ABRA and ABC urge that the production of blood products requires a uniform and exclusive set of federal standards.[4] But in fact, most of the arguments of appellee and ABRA are primarily concerned with why they think the FDA *ought* to preempt and not whether it *has* preempted. Whether or not exclusive federal control could be justified as a matter of policy is irrelevant to the issue of whether Congress or the FDA actually intended to preempt all complementary state and local regulation. The arguments concerning the need for absolute uniformity have been presented to the wrong branch of government; it should be Congress or the FDA that determines whether these claims have sufficient merit to take the extraordinary step of ousting all state and local regulation. Since they have not, this Court should not.

Nor is there any basis for inferring any regulatory intent to preempt merely from the existence of minimum standards.[5] ABRA argues that the FDA's standards rep-

[4] Amicus Grocery Manufacturers of America, Inc. is apparently concerned with the economic impact of the local ordinances. This issue arose at trial in the context of appellee's commerce clause challenge, but appellee's speculative evidence, which related most of the increased costs to a 25% decrease in the vendor population, was discounted by the District Court. J.A. 42-43, 46.

[5] Appellee relies heavily upon this Court's decision in *Ray* v. *Atlantic Richfield Co.*, 435 U.S. 151 (1978). But that case is fundamentally different from this one. In *Ray*, the Court held that *Congress* had impliedly and expressly preempted various state efforts to regulate the design or operation of oil tankers operating in navigable waters. Congress' dominant control over navigable waters was the essential basis for the Court's holding that some Washington State laws were preempted. In the Public Health Service Act, Congress has not impliedly preempted any local laws, as the FDA

resent a considered judgment as to the proper balance between the interest of safety on the one hand and the interest of ensuring an adequate supply of blood on the other. From this premise, ABRA asserts that Hillsborough County is precluded from modifying the FDA's judgment as to what standards are appropriate. If ABRA is correct, then all standards set by federal agencies will preempt state law. But the FDA has stated that it sees no threat to a healthy plasma supply posed by the county ordinances.[6] Every federal safety standard embodies a balancing of the amount of protection necessary for public welfare against the expense the regulation will impose on the regulated entity. Additional state and local regulation is valid nevertheless, unless Congress or the regulatory agency makes clear that the balance it has struck is meant to be exclusive and therefore cannot be modified by local law. See *California v. Zook*, 336 U.S. 725, 737 (1949); *Colorado Anti-Discrimination Comm'n v. Continental Air Lines, Inc.*, 372 U.S. 714, 722-724 (1963); L. Tribe, *Constitutional Law* 379 (1978). Because the FDA expressly stated that it did not intend to set absolute standards, this Court need not second-guess that judgment based solely on the FDA's decision to adopt additional minimum requirements.

III. Federal Regulatory Preemption of Non-conflicting Local Law Requires an Express Statement of Preemptive Intent.

Appellee argues (Br. 16-18) that the County and the *amici* National Association of Counties (NACo), *et*

in effect concluded in its 1973 regulations when it stated that states and localities could continue to regulate plasmapheresis centers.

[6] United States' Brief, pp. 27-28. One possible reason for the FDA's decision not to preempt in a case such as this is the rapidly developing advances in biotechnology, particularly recombinant DNA technology, which may allow the development of substitutes for a variety of plasma derivatives—such as the antihemophiliac factor—before the end of the decade. *See* Office of Technology Assessment, *Summary of Blood Policy and Technology*, Report H-260, at pp. 8, 29-32 (1985).

al., erroneously relied upon *Fidelity Federal Savings & Loan Ass'n v. De La Cuesta*, 458 U.S. 141 (1982), in arguing that regulatory agencies cannot *impliedly* preempt *non-conflicting* state and local regulation. Although the Court need not decide the issue because of the express statement of non-preemptive intent, the Court's prior decisions in *De La Cuesta* and *Capital Cities Cable, Inc. v. Crisp*, —— U.S. ——, 104 S. Ct. 2694 (1984), clearly indicate that an agency's intent to preempt the field must be expressly stated and the exercise of authority must be within the agency's delegated authority.

The cases cited by appellee (Br. 17-18) do not support a contrary rule. They all involved either situations where *Congress* had impliedly preempted the field in its delegations of authority to an agency or instances where the local laws actually have conflicted with the agency's regulations. But here Congress expressed no intent to preempt state or local plasmapheresis regulation and, contrary to the court's assertion, there is no real conflict between the County's ordinances and the FDA's regulations. See Part IV, *infra*. The County simply imposes additional obligations on plasmapheresis centers. Thus, this case clearly presents for the first time the issue of whether federal regulatory agencies can impliedly preempt the field, and, for the reasons stated in our opening brief and more fully set forth in the *amici curiae* brief of NACo, *et al.* (Br. 11-21), the Court should limit federal regulatory preemption of non-conflicting local law to situations where the agency expressly states in its regulation that it intends to exercise exclusive regulatory control.

IV. The County's Ordinances Do Not Conflict with the FDA's Regulations.

a. Appellee and ABRA attempt (App. Br. 17-18) to retry the case on the issue of whether the County's Ordinances conflict with the purposes or implementation of

the FDA's scheme. They cite appellee's evidence that was introduced in the district court to prove that the Ordinances would increase appellee's cost of doing business. They disregard, however, the district court's express *finding* that this evidence was too speculative to be credited. Thus, there is no factual basis for their claim that the Ordinances will adversely affect the supply of healthy blood.

Moreover, the County has concluded that the additional expense to plasmapheresis centers is necessary to protect the health of the residents of Hillsborough County. The FDA has not denied the County the right to exercise its police powers according to the County's best judgment. If the FDA perceives that local governments are regulating plasma centers too rigorously to the detriment of the nation's blood supply, then the FDA, after notice and comment, can adopt regulations expressly restricting the scope of local regulation. But until it does so, the County's public health interest remains paramount to appellee's and ABRA's interest in pursuing less costly practices that the County believes are potentially unsafe or unhealthy.[7]

b. The remaining claims of conflict are trivial and speculative and, in any event, were not relied upon by appellee in the lower courts. It is clear that none of the Ordinances' additional requirements conflicts with federal law.

First, the registration system will not reduce the amount of plasma a vendor can sell to a particular center; it will merely eliminate the vendor's ability to over-

---

[7] In this regard, ABRA's own examples (Br. 24) prove our point. If the FDA can decide to preempt expressly state efforts to regulate tamper-resistant drug packaging and warning labels on drugs for pregnant and nursing women, then it can expressly preempt local laws dealing with the plasma collection process. There is no need for this Court to declare preemption when the regulatory agency has not.

bleed himself by going from one center to another.[8] The cost of the identification card will merely require the individual who profits from selling plasma to share the County's cost of protecting his health and that of the employees of the plasma center. Moreover, if the vendors are truly, as ABRA's brief characterizes (Br. 5) them—"blue collar workers, housewives and university students"—then the County's regulations will not likely deter them from continuing to sell plasma.

Second, the breathalyzer requirement will only screen out people who should not be undergoing the plasmapheresis process anyway. Third, additional local in-

[8] ABRA (Br. 22 n. 36) claims that "[t]here was no evidence presented at trial that the Federal regulations are not adequate to prevent cross-donating." But there was unrebutted testimony of a plasmapheresis expert that the federal government did not develop a reliable registration system (Tr. 183-185), testimony of two FDA representatives that they do not cross check plasma center records in Tampa (Tr. 215, 224), and appellee itself stipulated prior to trial that it never exchanges records with other centers (R. 38, p. 17 ¶ 27).

ABRA argues (Br. 22) that the FDA's requirements that each donor be asked about prior bleeds, that he or she be examined for needle marks, and that protein and hemoglobin levels be tested prior to each bleed are sufficient to safeguard against cross-bleeding. Of course, an inquiry addressed to a person who has a monetary incentive to overbleed himself or herself cannot always be reliable. An examination for needle marks is not always reliable either, since a donor can legally have up to eight needle marks per month under the federal regulations.

Finally, the blood hemoglobin level test is meaningless for the determination of a previous *plasma* extraction, since hemoglobin is a part of the red blood cells which are returned in the plasmapheresis process. ABRA again cites part of an FDA statement to establish that the protein and hematrocrit tests "will indicate whether the donor has subjected himself to overbleeding." The complete sentence says that such tests would indicate whether a donor had subjected himself or herself to the overbleeding of *whole blood* or to plasmapheresis where the *red blood cells* were not returned to the donor. 38 Fed. Reg. 19364 (1973). This case only involves plasma.

spections will only ensure fuller compliance with both local and federal requirements. Certainly appellee cannot claim that the FDA's provision for limited inspections gives plasma centers the right to avoid detection of improprieties at other times.[9]

Both appellee and ABRA assert that the County's additional protections will have no positive health or safety consequences. But that is a judgment the FDA has expressly declared that the County should make and, as the district court found, the County reasonably responded to perceived health concerns in ways that were designed to protect the public welfare. The court of appeals' conclusion that the County's exercise of its police powers is impermissible under the Supremacy Clause of the United States Constitution is unfounded.

CONCLUSION

For the foregoing reasons and those stated in our opening brief, the judgment of the court of appeals should be reversed.

Respectfully submitted,

JOE HORN MOUNT
Counsel of Record
Hillsborough County Attorney
P.O. Box 1110
Tampa, Florida 33601
(813) 272-5670

EMELINE C. ACTON
Assistant Hillsborough
County Attorney

[9] Finally, the pre-screening requirement for hepatitis is simply not an issue in this case. Appellee makes no claim that it has standing to challenge this aspect of the County's Ordinances and therefore the Court should not reach out to decide the issue.